PB83-130294

Chemical Substances Designation
Volume I: Overview and Analysis

ICF, Inc.
Washington, DC

Prepared for

Environmental Protection Agency
Washington, DC

Dec 81

U.S. Department of Commerce
National Technical Information Service
NTIS

PB83-130294

TOXICS INTEGRATION POLICY SERIES EPA 560/TIIS-82-003

CHEMICAL SUBSTANCES DESIGNATION

VOLUME 1:

OVERVIEW AND ANALYSIS

Project Officer:

Arnold M. Edelman

Prepared under Contract No: 68-01-6038 for the

Office of Toxics Integration
Office of Pesticides and Toxic Substances
Environmental Protection Agency
December 1981

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA 22161

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO. EPA - 560/TIIS-82-003

2.

3. Recipient's Accession No. PB83 130294

4. Title and Subtitle

Chemical Substances Designation
Volume I: Overview and Analysis

5. Report Date December 1981

6.

7. Author(s) Bailey, et al

8. Performing Organization Rept. No.

9. Performing Organization Name and Address

ICF Incorporated
1850 K Street, N. W.
Washington, D. C. 20006

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C) 68-01-6038
(G)

12. Sponsoring Organization Name and Address

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Toxics Integration
Washington, D. C. 20460

13. Type of Report & Period Covered Informational

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This volume, part of a four volume study, examines EPA and other Federal agencies statutory and regulatory criteria for the designation of chemical substances. Volume I, a comparative analysis of the statutory authorities described in Volumes II and III, **focuses on** statutory purposes and goals, integration directives, the risks to be regulated, and the factors considered for designating and regulating chemical substances. The designation of chemical substances for regulation, hazard classifications and testing requirements are compared in the last section of Volume I. Volumes II and III review statutory provisions and regulations relating to the EPA and other Federal agency designation of chemical substances. The reviews focus on the criteria used to designate chemicals for regulation (e.g. role of economic and technological factors). The reviews specify which chemical substances are designated for regulation and each volume describes and analyze the hazard classification systems established and corresponding test methods required by the regulations. Volume IV, the chemical designation matrix provides a listing of the substances designated by regulation under the statues reviewed as they appear in the Code of Federal Regulations or the Federal Register (for proposed rules) as of January 1981.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement

19. Security Class (This Report)

20. Security Class (This Page)

21. No. of Pages

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

DISCLAIMER

The information included in this report include regulations or policies that were proposed or promulgated as of January 1, 1981 by the U.S. Environmental Protection Agency and other federal agencies. Because the regulations and policies described are subject to differing interpretations and their status may have changed since January 1, 1981, the reader is cautioned to view the materials in this light. In addition, this report is not intended to be a comprehensive up-to-date listing of all regulations or policies, but rather should be used to retrospectively understand how agencies designate chemical substances. The contents of this report were prepared under contract to EPA and, though reviewed by EPA and other agency staff, this review does not necessarily reflect the views and policies of the U.S. Environmental Protection Agency nor those of the other federal agencies whose authorities and regulations are reviewed.

Foreword

A major factor that contributes to integration of EPA as well as interagency activities on chemicals is understanding the purposes and major objectives that must be considered by each statute when designating chemicals for regulation. Because of the numerous statutes and regulations with differing purposes that designate hazardous materials, wastes or substances and toxic pollutants or substances, confusion often results.

The purpose of this four volume study is to lay out the key factors required by the statutes and their implementing regulations that must be considered when designating chemicals. The document serves as a ready reference to those faced with designing as well as complying with federal regulatory actions regarding chemicals.

Walter W. Kovalick Jr

Walter W. Kovalick, Jr.
Director
Integration Staff

Acknowledgements

The ICF Project Team owes much to the cooperation of EPA officials and staffs throughout the agency in providing helpful information, interpretations and comments. We particularly appreciate the guidance and enthusiasm of the Project Officer on this effort, Mr. Arnold M. Edelman, who originated the concept for this study and saw it through to completion. In addition, officials at other agencies, such as OSHA, DOT, FDA, CPSC, USDA, and the Nuclear Regulatory Commission also reviewed draft sections of this report, and their comments are appreciated.

The ICF Project Manager would particularly like to thank the Project Team members for their dedication and hard work and three individuals who managed the difficult task of production for the volumes comprising this report: Elizabeth Marshall, Suzanne Watkins, and Judy Lynn Lawson.

The Project Team consisted of:

Project Manager: Paul Bailey, J.D., M.P.P.
Senior Legal Associates: David Bruce, J.D., M.P.P.
Mike Goldman, J.D., M.B.A.
Associates: Lori Hashizume, M.S. (Economics)
Gilah Langner, M.P.P.
Robin Sandenburgh, M.P.P.
Ellen Taylor, M.P.P., Ph.D. (Biology)
Suzanne Watkins, M.P.P.
Research Assistants: Leslie Allen, Aaron Goldberg, Robert Irving,
Leonard Lapkin, Elizabeth Marshall
Subcontractor: Lawrence W. Bierlein, P.C.

VOLUME 1: TABLE OF CONTENTS

Page

EXECUTIVE SUMMARY ES-1

OVERVIEW OF THE STUDY 1

I. PURPOSES AND APPROACH 2

- A. PURPOSE OF THE REPORT 2
- B. STUDY LIMITS 3
- C. STUDY METHODOLOGY 4

II. BACKGROUND 9

III. PART 1: STATUTORY ANALYSIS 14

- A. OVERVIEW 14
- B. DESIGNATION AND STANDARD-SETTING DISTINGUISHED 14
- C. FRAMEWORK FOR ANALYSIS 18
  - 1. INTEGRATION--STATUTORY PROVISIONS REQUIRING CONSISTENCY WITH OTHER STATUTES 20
  - 2. ANALYSIS OF STATUTORY PURPOSES 25
  - 3. ANALYSIS OF STATUTORY DEFINITIONS OF HARMFUL SUBSTANCES 34
  - 4. DEFINITION OF THE RISK 40
    - (i) TYPE OF HARM 50
    - (ii) TYPE OF RISK 51
    - (iii) THE REQUIRED NEXUS OR CONNECTION: CERTAINTY, CAUSALITY, EFFECTIVENESS 62
  - 5. STATUTORY BASES AND FACTORS FOR LEVEL OF PROTECTION DECISIONS 74

IV. PART 2: REGULATORY ANALYSIS 87

- A. OVERVIEW 87
- B. ANALYSIS OF DESIGNATED CHEMICALS 88
  - 1. WHAT THE MATRIX SHOWS: AN OVERVIEW 88
  - 2. NAMING CONVENTIONS AND SYNONYMS 92
  - 3. DESIGNATION OF CHEMICAL GROUPS 95
  - 4. DESIGNATION OF COMPOUNDS 97
  - 5. DESIGNATION OF MIXTURES AND CONCENTRATIONS 99
- C. HAZARD CLASSIFICATION AND TESTING REQUIREMENTS 101
  - 1. TOXIC SUBSTANCES 104
  - 2. FIRE HAZARDS 115
  - 3. CORROSIVE HAZARDS 121
  - 4. REACTIVE HAZARDS 124
  - 5. RADIOACTIVE HAZARDS 130
  - 6. OTHER HAZARD CLASSIFICATIONS 134

V. APPENDIX A: SCHEMATIC DIAGRAMS OF KEY CHEMICAL DESIGNATION LAWS .. 139

VOLUME 1 LIST OF EXHIBITS

PAGE

EXHIBIT 1 FEDERAL LAWS CONTROLLING TOXIC SUBSTANCE EXPOSURES 10
EXHIBIT 2 USE OF DESIGNATION CRITERIA IN CHEMICAL CONTROL STATUTES... 16
EXHIBIT 3 SCHEMATIC OVERVIEW OF STATUTORY FACTORS AFFECTING REGULATORY AUTHORITY.................................... 19
EXHIBIT 4 MAJOR STATUTORY PROVISIONS FOR INTEGRATION................. 21
EXHIBIT 5 STATUTORY PURPOSES.. 26
EXHIBIT 6 CLASSIFICATION OF STATUTORY PURPOSES...................... 31
EXHIBIT 7 STATUTORY DEFINITION OF HARMFUL SUBSTANCES................. 35
EXHIBIT 8 RISK RATIONALE FOR DESIGNATION/REGULATION.................. 41
EXHIBIT 9 STATUTORY DESCRIPTION OF THE HARM.......................... 52
EXHIBIT 10 SAMPLE RANKING OF HEALTH EFFECTS CRITERIA.................. 55
EXHIBIT 11 RISK TERMS INCORPORATED IN STATUTORY PROVISIONS............ 56
EXHIBIT 12 TYPES OF CAUSAL CONNNECTIONS REQUIRED BETWEEN (1) CHEMICAL SUBSTANCES OR STANDARDS AND (2) RISK OF HARM... 65
EXHIBIT 13 REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION................................... 75
EXHIBIT 14 OVERVIEW OF STATUTORY RISK AND ECONOMIC CRITERIA........... 84
EXHIBIT 15 LEVEL OF PROTECTION AFFORDED BY CHEMICAL CONTROL LAWS...... 85
EXHIBIT 16 SOURCES OF DESIGNATED CHEMICAL SUBSTANCES.................. 89
EXHIBIT 17 DESIGNATION OF ARSENIC COMPOUNDS IN THE REGULATIONS........ 96
EXHIBIT 18 DESIGNATION OF ARSENIC COMPOUNDS IN THE MATRIX............. 98
EXHIBIT 19 DEFINITIONS OF PCB's...................................... 102
EXHIBIT 20 ACUTE TOXICITY PARAMETERS................................. 106
EXHIBIT 21 TOXICITY TESTS.. 108
EXHIBIT 22 FLASH POINT RANGES FOR LIQUID FIRE HAZARD CATEGORIES....... 116
EXHIBIT 23 DEFINITIONS OF SOLID FIRE HAZARDS.......................... 119
EXHIBIT 24 CORROSIVITY TESTS... 122
EXHIBIT 25 DEFINITIONS OF REACTIVE HAZARDS............................ 126

VOLUME 2 TABLE OF CONTENTS

PAGE

TOXIC SUBSTANCES CONTROL ACT

Statutory Review 1-1
Regulatory Review 1-22

CLEAN WATER ACT

Statutory Review 2-1
Regulatory Review 2-29

SAFE DRINKING WATER ACT

Statutory Review 3-1
Regulatory Review 3-9

MARINE PROTECTION, RESEARCH, AND SANCTUARITES ACT

Statutory Review 4-1
Regulatory Review 4-5

RESOURCE CONSERVATION AND RECOVERY ACT

Statutory Review 5-1
Regulatory Review 5-6

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Statutory Review 6-1
Regulatory Review 6-23

CLEAN AIR ACT

Statutory Review 7-1
Regulatory Review 7-35

COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT

Statutory Review 8-1

VOLUME 3 TABLE OF CONTENTS

PAGE

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Statutory Review.......... 1-2
Regulatory Review.......... 1-27

DEPARTMENT OF TRANSPORTATION

Statutory Review.......... 2-2
Regulatory Review.......... 2-9

FOOD AND DRUG ADMINISTRATION

Statutory Review.......... 3-2
Regulatory Review.......... 3-44

U.S. DEPARTMENT OF AGRICULTURE

Statutory Review.......... 4-2
Regulatory Review.......... 4-9

CONSUMER PRODUCT SAFETY COMMISSION

Statutory Review.......... 5-2
Regulatory Review.......... 5-32

NUCLEAR REGULATORY COMMISSION

Statutory Review.......... 6-2
Regulatory Review.......... 6-4

VOLUME 4 TABLE OF CONTENTS

PAGE

INTRODUCTION TO CHEMICAL DESIGNATION MATRIX.......................... 1

CHEMICAL DESIGNATION MATRIX.. 10

ADDENDUM.. 184

EXECUTIVE SUMMARY

I. PURPOSE OF THE REPORT

The purpose of this four volume report is to provide information and analysis useful in fostering intra- and interagency coordination on the designation of chemicals for regulation. This study examines both the statutory criteria for designation and classifying hazards and the designation of chemical substances in proposed or final regulations, as of January 1, 1981. It places a large number of statutory provisions into a common perspective and attempts to make them understandable.

The report serves as a baseline document for EPA's Office of Toxics Integration of the Office of Pesticides and Toxic Substances which is designing and facilitating the development of more integrated strategies for chemicals across the Environmental Protection Agency (EPA). These strategies draw on the authorities of all the appropriate statutes, including the Clean Air Act; Clean Water Act; Resource Conservation and Recovery Act; Safe Drinking Water Act; Toxic Substances Control Act; Federal Insecticide, Fungicide and Rodenticide Act; the Marine Protection Research and Sanctuaries Act; and the Comprehensive Environmental Response, Compensation and Liability Act. All of these Acts, in addition to Acts administered by the Occupational Safety and Health Administration, Consumer Product Safety Commission, Food and Drug Administration, Food Safety and Quality Service of the Department of Agriculture, Department of Transportation, and Nuclear Regulatory Commission, are included in the analyses and reviews comprising this report.

II. ORGANIZATION

The study is organized into four volumes:

- Volume 1 -- Introduction, Background, and Comparative Analyses
- Volume 2 -- EPA-Related Statutory and Regulatory Reviews
- Volume 3 -- Other Agency Statutory and Regulatory Reviews
- Volume 4 -- Chemical Designation Matrix

In Volume 1, the purpose and goals of the study are explained, the scope of work is specified, and the technical approach used to analyze the issue of designation is described. Volume 1 includes a comparative analysis of the statutory authorities described in Volumes II and III for the designation of chemicals for regulation. It focuses on statutory purposes and goals, integration directives, the risks to be regulated, and the factors considered for designating and regulating chemical substances. The designation of chemical substances for regulation, hazard classifications and testing requirements are compared in the last section of Volume 1 along with a discussion of those chemicals designated by regulation.

Volume 2 reviews statutory provisions and regulations relating to the EPA's designation of chemical substances for regulation. Volume 3 complements Volume 2 by reviewing relevant non-EPA statutes and regulations. The statutory and regulatory reviews in Volume 2 and Volume 3 focus on the criteria used to designate chemicals for regulation. The role of economic and technological factors in designation and standard setting is considered as well. The reviews specify which chemical substances are designated for regulation under the various statutory authorities. In addition, each volume describes and analyzes the hazard classification systems established and corresponding test methods required by the regulations.

Volume 4 contains the chemical designation matrix--a listing of the substances designated by regulation under the statutes reviewed here as they appear in the Code of Federal Regulations or the Federal Register (for proposed rules). The text describes how the matrix was produced, its uses, and the coding system employed. The matrix provides a reference for those wishing to know which chemical(s) have been designated as hazardous under various EPA and other Federal statutes through January 1, 1981.

III. STUDY LIMITS

The focus of the report is exclusively on chemical regulatory designation issues at the Federal level, thus excluding consideration of enforcement actions, research priorities, state plan guidance, and the issuance of permits, variances, exemptions, exceptions, waivers, etc. In addition, regulatory authority relating to standards of effectiveness, purity standards, labeling (apart from cautionary labeling) standards, and the like which pertain to purely economic considerations (e.g., the product must be substantially as advertised) were not included. Also excluded are routine reporting requirements or other standards premised on use or production of certain chemicals and hazardous micro-organisms or similar biological entities.

In addition, certain issues and areas have been explicitly excluded from the scope of this study. These include:

- Agency "policies" are generally not included in the scope of the study. Only EPA's proposed airborne carcinogen policy and OSHA's proposed workplace carcinogen policies were reviewed. The designation matrix is therefore limited to formally proposed or already promulgated regulations.

- Designation of toxic chemicals by nongovernmental groups, such as the National Fire Protection Association or the Association of American Railroads, is not included in the scope of the study.

Finally, it was not feasible to conduct an in-depth analysis of all the regulations designating or naming chemical substances. Aside from the absolute numbers of substances involved, other complicating factors include differences in statutory criteria for designation; variations in the level of hazardous presented by the same substance in different environmental media; inconsistent use of identifiers and naming conventions; varying priorities among the different regulatory programs; and varying levels of scientific uncertainty regarding risk potential of chemicals.

Therefore, the analysis of chemical substances designated by name for regulation by January 1, 1981, takes the form of a discussion of key issues and problems using specific examples as illustrations. The discussion is not exhaustive. In most cases, the examples used were derived from the creation and review of a "matrix" (presented in Volume 4) which collects the various substances designated.

In contrast, the analysis of hazard classifications and associated testing requirements is more comprehensive. Again, only hazard classifications proposed by January 1, 1981 are included, with the exception of the OSHA labelling standard which was both proposed and withdrawn during January of 1981; it is included in the analysis for information only. Testing requirements which are part of hazard classifications are analyzed; however, many other specific testing standards exist which did not fall within the scope of this contract.

To insure accuracy, the statutory and regulatory reviews discussed in Volumes I, II and III were subjected to EPA and other Agency examination and comment. The contractor reviews and conclusions, however, do not necessarily reflect the views and policies of the U.S. Environmental Protection Agency nor of the other federal agencies whose authorities and regulations are reviewed.

IV. STATUTORY AND REGULATORY ANALYSIS

Following is an overview of the major findings of the study which are discussed in detail in Volume I.

A. Statutory Analysis

Despite many specific variations in statutory language of over 30 distinct provisions reviewed for the report, certain concepts reoccur: risk, benefit, technical and economic factors all play important roles in determining regulatory authority to designate and regulate chemicals. The analysis covers the key statutory provisions of the laws included in the study, and considers

1) statutory purposes, 2) definitions of harmful substances, 3) risk criteria, 4) required considerations, and 5) integration directives.

Before discussing the key provisions of the laws, it is important to clarify the use of two key terms "designation" and "regulation." The former should be thought of as a threshold process of identifying hazards that can be distinguished from the crafting of regulatory "standards." Designation may be thought of as the identification of the problem (i.e., identifying a specific chemical as one that can cause adverse effects via certain exposures). Regulation, or standard-setting, may be thought of as the crafting of solutions to the problem (i.e. requirements for specific action when exposure to the designated chemical occurs). Both designation and regulation may be governed by distinct criteria and subject to different standards of review. Typically, designation criteria are phrased in terms of potential health effects (i.e., toxicity) or risks presented by a substance. Regulatory criteria are often defined by such terms as "feasibility," "best available technology," "margin of safety," "taking cost into account." The main focus of this study is on the designation of chemical substances as "toxic," "hazardous," or otherwise subject to federal regulation. However, because many laws do not provide distinct designation criteria, this study also analyzes regulatory criteria.

All regulated chemicals are designated in one way or another. However, the definitions used in agency regulations may not be specific enough to identify all substances subject to regulation. This is particularly a problem when categories or generic terms are used; it is unclear whether unnamed isomers or compounds are meant to be regulated or not. Oftentimes, a substance (e.g., lead arsenate) may be eligible for regulation under two different standards (e.g., the standard for lead compounds or the standard for arsenic compounds), although the regulations may contain no guidance for resolving the problem. In other cases, the chemical definition may be clear, but other factors (e.g., size cutoffs for asbestos fibers) may cause regulatory inconsistencies. Designation, then, is an inherent part of standard-setting, but may also be a separate and independent administrative action.

1. Statutory Purposes

Fundamental to an analysis of statutory authorities for designating chemical substances is a careful assessment of the purposes for which the statutes were developed. Each statutory purpose directs the regulatory effort to one or more particular concerns, and sets priorities for accomplishing the goals outlined in the statute. Such purposes may be explicit or implied. An understanding of the differences between statutory purposes is very useful in attempting to understand the differences in the legal authorities for designation of hazardous substances.

In particular, notable differences exist among the core purposes of the EPA statutes. The acts' purposes range from the broad protection of health and environment (RCRA, CERCLA, TSCA) to only human health (SDWA) to protection of a specific environmental medium (CAA, CWA). The terms "restore," "improve," and "enhance" unique to the CWA, CERCLA, and CAA imply a more active government role than the term "protect." On the other hand, the statutory purpose forms just one element in the analysis of regulatory authority. Volume 1 analyzes each purpose relevant to health and safety regulation as it appears in the statute. It is noteworthy that not all statutes explicitly state their purpose.

2. Definitions of Harmful Substances

One of the key factors shaping the regulatory authority of a statute is the definition of those substances subject to designation and/or regulation. Agency authority is effectively circumscribed by these definitions.

Volume 1 compares the definitions included in the statutes reviewed. The analysis focuses on criteria used in definitions of harmful substances, where this is provided (e.g., the RCRA definition of hazardous wastes). Where a separate category is not included in the statute, the definitions of the general category of substances subject to regulation (e.g., "materials" under MPRSA, "pesticides" under FIFRA) are identified. In the latter case, the statutes typically include other provisions and criteria tying designation and regulation to some definition of harm to be avoided.

3. Risk Criteria

After reviewing both the statutory authorities and some of the case law which attempt to interpret these difficult provisions, several distinct aspects of this parameter were identified: (1) type (or magnitude) of harm involved; (2) degree of certainty required; (3) the required causal connection between the substance, regulation, and the harm; (4) the probability of the harm (i.e., magnitude of the risk); and (5) the type of risk subject to control (e.g., unreasonable risk).

For convenience, the analysis groups these aspects of risk into three parts:

(1) Type of harm involved, which is more or less explicitly described in the statute and/or subsumed under risk terms;

(2) Type of risk involved, which includes the magnitude (i.e., probability) of the risk as well as the type of risk subject to control (e.g., unreasonable risk);

(3) Required nexus or connection between the substance, regulation, and the harm or risk involved, which is described by statutory terms relating to probability, uncertainty, and causality. (e.g., reasonably anticipated, pose or present)

Not every statute incorporates all of these aspects. And the statutory terms used tend to overlap and be ambiguous, at times. Distinguishing these aspects for the purpose of comparative analysis may seem like a confusing exercise in semantics and legal interpretation. However, statutory idiosyncracies in defining risks prevent a simpler approach.

4. Required Considerations

Statutory language often guides the designation and standard-setting process by explicitly providing a specified basis for making decisions as well as factors to be considered. In discussing these issues, it is essential to distinguish among:

- bases for decisions,
- factors which must be considered,
- factors which may be considered, and
- factors which may not be considered.

In addition, the statutes reviewed often differ as to the amount of protection or risk reduction they authorize. Many statutes refer only to the issuance of standards "necessary," "adequate," "desirable" or "sufficient" to protect the public health. Some give more detailed guidance (e.g., ample margin of safety, no material impairment of health). Others address this issue by prescribing particular factors as the basis for standard-setting (or as matters for consideration). These laws allow for the balancing of risk and cost considerations, as another way of establishing a level of protection. Volume I identifies those provisions and distinguishes among risk, economic and technical bases for regulatory actions.

5. Integration Directives

The report identifies legal provisions concerning interagency and intra-agency integration (e.g., coordination, cooperation, consultation) in the designation of hazardous chemicals. Experience with these provisions and with regulatory integration is limited. However, there is anecdotal evidence which indicates that specific Congressional directives can facilitate the promulgation of integrated regulations.

B. Regulatory Analysis

There are two different ways that chemical substances can be designated and regulated. One approach is to identify and list specific chemical substances in the applicable regulations. The other approach is to identify the harmful characteristics or effects (hazard classification) which would qualify a chemical for regulation, leaving it up to private industry to determine (test) which substances have such characteristics or effects. While each approach has particular problems, regulatory programs frequently use both approaches (e.g., RCRA, DOT, FIFRA).

1. Identification and Listing

In order to compile all various chemicals designated, a chemical designation matrix listing those substances designated by name in all the agency reguations which were reviewed was devised. In addition to listing all chemicals, the matrix also highlights designation problems. Different naming conventions, incomplete and overlapping chemical groups, lack of synonyms, and different treatment of compounds and mixtures all make it very difficult to follow one substance through several regulations. The matrix lists hundreds of chemicals designated by Federal agencies.

The primary factors that determine which substances are designated are the regulatory authority embodied in statutory risk criteria and the available scientific evidence. Thus, it is difficult to make analytical inferences from the matrix. Just because a substance is listed does not mean it is unsafe in all uses or exposures. Conversely, just because a substances has not been designated does not mean that it is safe in all uses or exposures. The use of or the environment affected by a particular substance may determine its classification. For example, a chemical in food dyes may be classified as toxic, whereas the same chemical used in pesticides may not be. Also, the assumptions that agencies make concerning risk assessment are likely to vary. These assumptions concern such issues as dose relationships, margins of safety, and models of data extrapolation, and may affect which chemicals are designated as hazardous. Finally, the manner in which agencies view exposure levels to substances may vary. Some agencies may consider the effects of chemicals as additive; other agencies consider the effects of chemicals individually, as if humans were exposed to chemicals in the absence of other exposure routes.

Despite the difficulties in comparing the designation of hazardous substances, the form of the matrix emphasizes several important aspects of the way agencies designate chemicals.

- use of differing naming conventions and definitions, and limited use of synonyms for listed substances

The variety of naming conventions would not necessarily be a significant problem if the regulations themselves provided suitable cross-references to synonyms. They do not. In fact, tracing the regulatory status of a particular chemical is often quite difficult. FWPCA §307 regulations do not generally identify synonyms, while FWPCA §311 regulations do list all synonyms of each substance, whether there are two names or five for one chemical substance. HMTA regulations usually list only one name, except in a few instances where two names are listed. RCRA regulations list some synonyms, but not all of the time. FIFRA regulations often do not adequately cross-reference brand names to chemical names. This problem is compounded by the alternative ways that chemicals are designated in groups.

- use of generic terms designating groups of substances

The use of generic categories further complicates the analysis of designation. Designation of a class of chemicals (e.g., chlorinated benzenes) can subsume many individual substances. The problem arises when agencies define or interpret designated chemical groups in different ways.

- Differing approaches to the designation or inclusion of compounds, isomers, etc. and the treatment of mixtures.

A basic uncertainty is the definition (or lack of a definition) of the word "compound." An agency designates a chemical, such as arsenic, as hazardous, and then may or may not list ~~or~~ otherwise include its compounds, isomers, hydrates, or mixtures. On the other hand, the regulations may specify that the element or compound specifically listed includes other forms.

Agencies also give categories special definitions that do not clearly follow the category name. For example, under OSHA §6b, "inorganic arsenic" includes "copper aceto-arsenate, and all inorganic compounds containing arsenic except arsine, measured as arsenic" (29 CFR 1910.1018(b)). Copper aceto-arsenate, in a strict sense, is not an inorganic chemical, because it contains organic carbon. Arsine, on the other hand, would normally be considered an inorganic arsenic compound. When comparing the OSHA designation with FWPCA §311, which also covers inorganic arsenic compounds, it is clear the latter does not utilize the same definition as OSHA.

2. Hazard Classification and Testing Requirements

Many regulations designate not only specific chemicals, but also characteristics of chemicals, as hazardous. The use of characteristics or classifications has several advantages. First of all, under these rules, it is usually the responsibility of industry to test specific chemicals and mixtures of chemicals for dangerous properties. Secondly, this "generic approach" results in far more comprehensive coverage than listing individual substances, since all materials--not just those materials that the agencies are aware of and have the resources to analyze--must be evaluated against the hazard criteria. Finally, specifying general types of dangers also provides structure to the regulations. Labeling and handling requirements are frequently organized according to hazard so that substances that pose similar risks are treated in similar fashion. In this way, hazard classes may determine how, as well as which chemicals are regulated.

In establishing generic hazard classifications agencies have set up (1) exact, testable categories, (2) more general descriptive definitions and, (3) in some instances, no definitions at all. Precise categories that are delineated by standard physical, chemical or biological tests, such as flash-point ranges, appear to be the most useful. In many cases, however, there are no reliable or comprehensive tests that cover all of the substances, that, for proper handling, should be grouped in one category.

The different agencies, mandates, and methods have resulted in differing classifications, testing requirements, and test levels that regulated industry must satisfy. Some attempts have been made to coordinate regulations; for instance between EPA under RCRA and DOT under HMTA. However, differences exist both among and within different agencies' programs. One important reason for this is the fact that each regulation controls a different type of exposure--a characteristic which is hazardous in one medium (e.g., consumer products) may not be deemed hazardous in another for which public exposure is smaller (e.g., solid waste).

The analysis in Volume 1 shows the kinds of classification used and what tests must be satisfied. Hazard categories (and associated testing requirements), that have been established by seven different agencies under nineteen separate statutes are reviewed. The analysis covers the following generic hazardous classifications:

- Toxic Substances
- Fire Hazards
- Corrosive Hazards
- Reactive Hazards
- Radioactive Hazards
- Other Hazard Classifications

Volume I reviews each of these classifications, discusses the criteria and testing required, and identifies similarities and differences. For example,

- the same tests for metal corrosion are used by EPA and DOT

The two regulations which cover metal corrosion require identical steel corrosion tests. The RCRA test was taken directly from DOT Hazardous Materials rules after EPA determined that the Agency's "concern about container damage is identical to that of DOT's."

- use of differing ranges, characteristics and testing to determine fire hazards.

Under RCRA, FIFRA, HMTA, Coast Guard and OSHA, various flammability definitions and testing methods have been established. The flash point ranges which define the classes under the various programs differ according to the temperatures normally incident to handling the respective materials. For example, the 140°F "ignitability" criterion established under RCRA was chosen specifically to relate to "the potential sources of ignition existing at a landfill site, such as hot truck exhaust pipes and heat from neutralization reactions."

The regulations differ not only in the flash point ranges used to define the hazard categories, but also in the test methods authorized for determining the ignition temperatures. Most of the classifications require the use of "closed-cup" tests (Pensky-Martens, Setaflash, or Tagliabue), while FHSA and USCG mandate use of an open cup test, which typically gives higher flash point results.

V. CONCLUSIONS

The many laws authorizing regulation of hazardous chemicals contain numerous differences in statutory language and criteria. Although some of these differences may be insignificant, other differences are substantive. These requirements may be found in provisions defining the substances to be regulated, the purposes of the legislation, the risk criteria, factors or bases for decisions, and directives for integrating regulations with other programs. Risk, technical, and economic considerations -- and relationships between and among these factors -- appear in various combinations and guises. The analysis of statutory language in Volume 1 and the reviews contained in Volumes 2 and 3 can be used to identify key language as well as judicial interpretations, if any, and agency implementation.

Regulations designating hazardous chemicals use both hazard classifications (e.g., flammables) and lists of covered chemicals and synonyms to identify substances meant to be included. In the case of hazard classifications, a number of technical and terminological inconsistencies exist; similar problems occur with the use of lists -- different naming conventions, incomplete synonyms, overlapping generic designations, and ambiguity over the designation of compounds are not uncommon. The regulatory analyses in Volume 1, the reviews in Volumes 2 and 3, and the chemical designation matrix in Volume 4 can be used to identify what chemicals have been designated and how, in addition to the hazard classifications and testing requirements proposed or effective as of January 1, 1981.

This report does not focus on nor emphasize the overall consistency of Federal regulations dealing with designation of hazardous chemicals. In general, Federal regulations do not conflict. However, complicating factors such as different statutory mandates and/or differences in the regulatory environment (e.g., transportation conditions, disposal concerns, or varying chemical properties) often prevent identical chemical lists, performance standards, etc. These differences can be appropriate. On the other hand, this report attempts to identify potential inconsistencies for further consideration as opportunities for better integration.

OVERVIEW OF THE STUDY

Statutory authorities for designating chemical substances for government regulation are scattered among many federal laws and regulatory agencies. The purpose of this report is to review and analyze all these laws, focusing on the specific statutory criteria and regulatory requirements for designating chemical substances.

The report is organized into four volumes:

- Volume 1 -- Executive Summary, Background and Comparative Analyses
- Volume 2 -- EPA-Related Statutory and Regulatory Reviews
- Volume 3 -- Other Agency Statutory and Regulatory Reviews
- Volume 4 -- Chemical Designation Matrix

In addition to an executive summary, Volume 1 contains an overview of the study, a discussion of its purpose and the approach used, background information, the statutory analysis, the regulatory analysis, and an appendix containing schematic diagrams of key laws. The statutory and regulatory analyses compare and contrast material compiled in the statutory and regulatory reviews comprising Volumes 2 and 3.

Volume 2 reviews statutory provisions and regulatory requirements relating to the Environmental Protection Agency's designation of chemical substances for regulation. The following EPA authorities are reviewed:

- Toxic Substances Control Act
- Federal Water Pollution Control Act
- Safe Drinking Water Act
- Marine Protection, Research and Sanctuaries Act
- Resource Conservation and Recovery Act
- Federal Insecticide, Fungicide, and Rodenticide Act
- Clean Air Act
- Comprehensive Environmental Response, Compensation and Liability Act.

Volume 3 complements Volume 2's coverage of EPA authorities by reviewing relevant non-EPA statutes and regulations. The following agencies' statutory authority to designate and regulate chemical substances are reviewed:

- Occupational Safety and Health Administration
- Department of Transportation/United States Coast Guard
- Food and Drug Administration
- United States Department of Agriculture
- Consumer Product Safety Commission
- Nuclear Regulatory Commission

The statutory and regulatory reviews in Volume 2 and Volume 3 focus on the criteria used to designate chemicals for regulation. For example, the designation of some chemicals may be based on human toxicity, whereas other chemicals may be designated because of their toxicological effects on aquatic organisms. The role of economic and technological factors in designation and standard setting is considered as well. The reviews also specify which chemical substances are designated for regulation under the various statutory authorities.

Volume 4 contains the chemical designation matrix--a listing of the substances designated under the statutes reviewed here as they appear in the Code of Federal Regulations or the Federal Register (for proposed rules). The text describes how the matrix was produced, its uses, and the coding system employed.

I. PURPOSE AND APPROACH

PURPOSE OF THE REPORT

The purpose of this report is to provide information and analysis useful in fostering intra- and interagency coordination concerning the designation of chemicals for regulation. This study examines statutory bases for designation, classification of hazards, testing requirements, and the designation of chemical substances in proposed or final regulations, as of January 1, 1981. The report places a large number of statutory provisions into perspective and attempts to make them understandable.

The goal of fostering intra-agency coordination concerning the designation of chemicals for regulation is an agency priority which is being implemented by the Office of Toxics Integration of the Office of Pesticides and Toxic Substances. The agency's goal is to develop integrated strategies, drawing on authorities of one or more appropriate EPA statutes, including the Clean Air Act; Clean Water Act; Resource Conservation and Recovery Act; Safe Drinking Water Act; Toxic Substances Control Act; Federal Insecticide, Fungicide and Rodenticide Act; the Marine Sanctuaries and Protection Act; and the Comprehensive Environmental Response, Compensation and Liability Act. All of these Acts are included in the analyses and reviews comprising this report.

The scope of this study also includes the examination of other laws governing toxic substance hazards used by the EPA and the Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), Department of Transportation (DOT), Nuclear Regulatory Commission (NRC), Department of Agriculture (USDA), and the Consumer Product Safety Commission (CPSC). The focal point of the study remains the EPA. The study does not extensively consider issues of interest only to the other agencies (e.g., DOT-NRC coordination in designating radioactive substances).

STUDY LIMITS

Certain issues and areas have been explicitly excluded from the scope of this study. These include:

- Agency "policies" are generally not included in the scope of the study. Only EPA's proposed airborne carcinogen policy and OSHA's proposed workplace carcinogen policies have been reviewed. The designation matrix is limited to formally proposed or already promulgated regulations.

- International (e.g., IMCO, OECD) rules and conventions are not included in the scope of the study. Inconsistencies and conflicts between federal rules and international requirements have not been systematically investigated.
- State actions relating to designation have not been included. Only federal statutes and regulations have been analyzed.
- Designation of toxic chemicals by nongovernmental groups, such as the National Fire Protection Association or the Association of American Railroads, is not included in the scope of the study.

Moreover, the focus is exclusively on regulatory designation issues, thus excluding consideration of enforcement actions, research priorities, state plan guidance, and the issuance of variances, exemptions, exceptions, waivers, permits, etc.

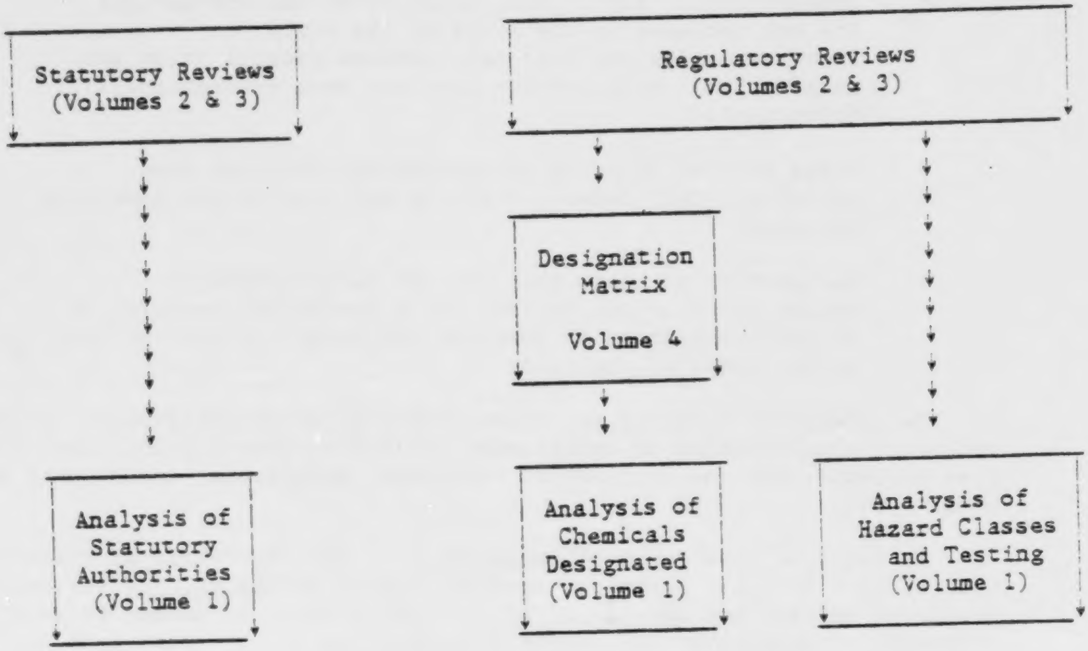
In addition, the focus is exclusively on the regulation of substances with respect to their potential adverse effects on health, the environment, or property; we have not considered or reviewed regulatory authority relating to standards of effectiveness, purity standards, labeling (apart from cautionary labeling) standards, and the like which pertain to purely economic considerations (e.g., the product must be substantially as advertised). Nor have routine reporting requirements or other standards premised on use or production of certain chemicals been systematically included. Also, hazardous micro-organisms or similar biological entities are not included in the review; only non-living chemical substances are considered.

STUDY METHODOLOGY

The approach used to prepare this study can be described quite simply as consisting of three parts:

(1) Statutory Reviews
(2) Regulatory Reviews
(3) Statutory and Regulatory Analyses

The statutory reviews formed the input to the analysis of statutory authorities. The regulatory reviews formed the basis for the comparative analysis of hazard classification and testing requirements as well as the analysis of chemicals designated. The interrelations among these tasks can be shown graphically:


Statutory Reviews (Volumes 2 & 3)
Regulatory Reviews (Volumes 2 & 3)
Designation Matrix Volume 4
Analysis of Statutory Authorities (Volume 1)
Analysis of Chemicals Designated (Volume 1)
Analysis of Hazard Classes and Testing (Volume 1)

To insure accuracy, the statutory and regulatory reviews were subjected to agency examination and comment. The reviews can be found in Volumes 2 and 3 of this report. The designation matrix is included in Volume 4. The analyses are presented in Volume 1. ICF's approach to each of the major tasks is summarized below.

Statutory Reviews

As noted earlier, this study analyzes the statutory provisions for designating chemical substances enacted by January 1, 1981. The legal analysis of statutes required the review of:

- the statute itself
- its legislative history
- Congressional committee reports
- court cases (and settlements) construing the statute
- administrative interpretations
- law review articles
- treatises and other commentary

The statutory authorities listed in Exhibit 1 (above) were reviewed.

The statutes were reviewed to determine general and/or specific mandates and authorities to identify and regulate chemicals as hazardous to human health and/or the environment. In addition, ICF examined the following aspects of the statutes:

- statutory purpose;
- chemical substances covered;
- integration mandates;
- definitions of "hazardous" and "toxic" substances;
- kind of harm sought to be avoided;
- level of causality and certainty required;
- criteria for designation and standards, (e.g., toxicity, benefit/cost considerations, margin of safety).

Reported legal cases interpreting relevant statutory language were analyzed, emphasizing administrative and policy implications of decisions. ICF described the legal basis and rationale for each important judicial decision, its precise holding(s), findings, and implications. "Dicta" were carefully distinguished from language having precedential value. Historical material was included only as necessary.

Furthermore, ICF determined whether statutory provisions were judicially tested or otherwise affirmed. For example, the scope of DOT authority in designating materials as hazardous has not been judicially reviewed.

Regulatory Reviews

Virtually all regulations that relate to the designation of chemical substances promulgated or proposed by January 1, 1981 were reviewed for this study. ICF examined and summarized all notices of proposed and final rulemakings, including agency preambles. Relevant criteria documents (e.g., Air Quality and Water Quality Criteria Documents) were reviewed, particularly for information about specific factors used to designate and regulate substances. Reported legal cases reviewing the regulations were analyzed for their substantive implications regarding agency discretion to designate chemicals for regulation. Finally, discussions with agency staff and their comments on the draft contributed to the research base.

The regulatory review required the examination of:

- the chemicals designated or listed;
- criteria for selection (e.g., health effects);
- definitions;
- naming conventions;
- quantity limits and concentrations;
- basis for standards (e.g., technology, toxicity).

Analysis of Statutory Authorities

The methodology followed in performing this analysis is relatively straightforward.

First, ICF identified the key issues to be included in the analysis. The following issues were selected.

- statutory purpose--this was selected because courts typically refer to a statute's goals when interpreting agency regulatory authority
- integration directions, guidance, or constraints--this was selected because several statutes make some type of provision for integration, coordination, or consultation
- risk to be avoided--this issue is crucial in determining the scope of statutory authority and has several components: the severity, probability, type, and certainty (i.e. causality) of harm
- factors for designating and regulating substances--this issue likewise is crucial for analyzing the role of economic and technical factors

An in-house "questionnaire" was then used to organize the material reviewed by the project team for the analysis of these issues. Both the statutory and regulatory reviews served as sources for the information needed.

Chemical Designation Matrix Analysis

The study team reviewed the chemical substances designated for regulation by constructing a "matrix" showing which chemical substances have been designated under which statutory authorities. The matrix provides an overview of the scope of government regulation of toxic chemicals. Use of the matrix can facilitate identification of nomenclature problems in toxic chemical regulations. These and related issues are discussed in more detail later in Volume 1.

Analysis of Hazard Classifications and Testing Requirements

The ICF study team compared and reviewed the various hazard classifications and tests that are required under different agencies and EPA programs. Regulations under each act often include different classifications, leading to conflict among various categories. Test requirements, in the form of such things as the number of animals used, how the results should be measured, and the type of test method employed, are often a critical part of the definition of each category. In this analysis ICF reviewed each classification with its associated tests and discussed how the regulations under each statute dealt with various classifications, if at all. Exhibits comparing the different classifications are provided.

II. BACKGROUND OF THE STUDY

Chemical substances are properly designated "hazardous" and subject to government regulation as a result of the risks they pose to human health and safety and to the environment. These risks result from manufacture or processing (worker exposure, environmental release, disposal, spills, fugitive emissions), transport (spills, fugitive release, worker exposure during loading and unloading), and consumer use. Exposure may be to hazardous consumer products, chemicals, feedstocks, intermediates, by-products, and wastes. Risks from multiple exposures and unpredictable synergistic effects complicate designation decisions.

In most instances, risks are probabilistic; that is to say, not everyone will be exposed nor will everyone exposed suffer adverse consequences. Moreover, in all instances, there remains much scientific uncertainty concerning such important issues as:

- exposed population at risk
- dose-response relationships
- threshold levels
- magnitude, scope, and certainty of health effects

Not only is the available scientific data often inadequate, but even methodologies for risk-assessment may not be well-suited to analyzing risks imposed by chronic low-level exposures having latent effects under conditions of considerable uncertainty.

Understandably, the regulation of hazardous chemicals has tended to emphasize acute effects. The risks posed by explosives, poisons and corrosives are easier to understand; control measures are easier to evaluate; and health and safety effects are easier to test and monitor. However, the past ten years have witnessed a profound change. There is an increasing awareness and concern about carcinogenic and reproductive hazards, the chronic risks they pose, the cost of controls. The result has been a flurry of legislative activity oriented around the protection of human health and safety and the environment. Exhibit 1 presents an overview of federal statutes concerned with toxic substance control.

The laws listed in Exhibit 1 recognize that hazardous chemicals may be encountered on the job, in the environment, in household and consumer products, in food, drugs, and cosmetics, and in drinking water. Exposures may be direct or mediated. Toxic substances may move through the food chain; they can migrate from storage lagoons and dumps into wells and streams; they can penetrate packaging; they can be inhaled, ingested, or absorbed throughout the product cycle from synthesis to preparation, through processing, distribution,

EXHIBIT 1

FEDERAL LAWS CONTROLLING TOXIC SUBSTANCE EXPOSURES

Statute	Agency	Coverage
Clean Air Act (1970, amended 1977)	EPA	Air pollutants
Federal Water Pollution Control Act (1972, amended 1977, 1978)	EPA	Water pollutants
Safe Drinking Water Act (1974, amended 1977)	EPA	Drinking water contaminants
Federal Insecticide, Fungicide and Rodenticide Act (1948, amended 1972)	EPA	Pesticides
Pesticide Residues Amendment[1] (1954, amended 1972)	EPA	Pesticide residues in food
Marine Protection, Research and Sanctuaries Act (1972)	EPA	Ocean dumping
Resource Conservation and Recovery Act (1976)	EPA	Hazardous wastes
Toxic Substances Control Act (1976)	EPA	All chemical hazards not covered by other laws[2]
Comprehensive Environmental Response, Compensation, and Liability Act (1981)	EPA	Hazardous substances, pollutants and contaminants
Occupational Safety and Health Act (1970)	OSHA	Workplace exposures
Food, Drug and Cosmetic Act (1932)	FDA	Food, drugs, cosmetics

---

[1] Codified as Section 346(a) of the Food, Drug and Cosmetic Act.

[2] Also requires pre-market evaluation of all new chemical substances except food additives, drugs, pesticides, alcohol, and tobacco.

EXHIBIT 1 (continued)

FEDERAL LAWS CONTROLLING TOXIC SUBSTANCE EXPOSURES

Statute	Agency	Coverage
Food Additives Amendment (1958)	FDA	Food additives
Color Additive Amendments (1960)	FDA	Color additives
New Drug Amendments (1962)	FDA	New drugs
New Animal Drug Amendments (1968)	FDA	Animal drugs and feed additives
Medical Device Amendments (1976)	FDA	Medical devices
Wholesome Meat Act (1967) Wholesome Poultry Products Act (1968) Egg Products Inspection Act (1970)	USDA	Food, feed, color additives, and pesticide residues
Federal Hazardous Substances Act (1966)	CPSC	Toxic household products
Consumer Product Safety Act (1972)	CPSC	Dangerous consumer products
Poison Prevention Packaging Act (1970)	CPSC	Packaging of dangerous products
Lead-Based Paint Poison Prevention Act (1973, amended 1976)	CPSC	Lead paint in federally-assisted housing
Hazardous Materials Transportation Act (1970)	DOT	Transportation of hazardous materials
Ports and Waterways Safety Act (1972)	DOT-USCG	Water shipment of toxic materials
Dangerous Cargo Act (1952)	DOT-USCG	Water shipment of toxic materials
Atomic Energy Act (1954)	NRC	Radioactive substances

and transportation, to incorporation into products and final disposal. Fugitive emissions, emergency releases and unintentional spills all contribute to possible exposures.

Legislation enacted episodically by Congress as it perceived specific needs for additional controls has resulted in the complex of hazardous chemicals statutes listed in Exhibit 1. As a result, many widely used substances fall under the jurisdiction of more than one law within an agency and more than one federal agency:

- For example, a dozen substances have each been designated for regulation under seven or more separate authorities as of January 1, 1981, (acrylonitrile, aldrin, asbestos, benzene, cadmium, chlordane, DDT, endrin, heptachlor, lead, mercury, vinyl chloride).[1]
- The full regulation of all sources of exposure to vinyl chloride would involve action by five different agencies operating under 15 statutes.[2]
- Two or more member agencies of the Interagency Regulatory Liaison Group (IRLG) were involved in the regulation of 21 different hazardous materials.[3]
- Several agencies administer more than one toxic substance control program.

Compliance on the part of the regulated community may be rendered more difficult and costly because of jurisdictional fragmentation. Businesses may find themselves the object of multiple requirements of several different federal laws and agencies. Oftentimes, control measures designed to reduce one type of exposure (e.g., workplace standards) may result in increases of other types of exposures (e.g., air emissions or solid waste).

The fragmentation of agency jurisdiction also has been credited with encouraging protracted litigation both by industries desiring to be regulated under a less stringent authority and also by public interest groups desiring regulations under a more stringent standard.[*/] This sort of litigation results when the relevant agency statutes differ on issues such as the burden of proof and the consideration of economic factors.

---

[1] Chemical Substances Designation, Volume 4 (1981).

[2] Doniger, "Federal Regulation of Vinyl Chloride: A Short Course on Toxic Substances Control Law and Policy," 7 Ecology Law Quarterly 498-658 (1978).

[3] Regulatory Reporter, Interagency Regulatory Liaison Group, December 1980.

In addition to inter-agency jurisdictional problems, there are also important coordination problems within agencies. The EPA administers a number of extensive regulatory programs under eight separate statutes, not including the recently enacted Comprehensive Environmental Response, Compensation, and Liability Act. Within a single act such as the Clean Air Act, separate criteria are listed for new sources, existing sources, mobile sources, hazardous pollutants, etc. Chemicals may constitute different priorities in different media control strategies for purely technical reasons. Thus, the problems of jurisdictional conflicts and duplicative/inconsistent actions can be as serious within an agency as they are between agencies.

[*/] Doniger, Liroff and Dean, "An Analysis of Past Federal Efforts to Control Toxic Substances" (Environmental Law Institute, Final Report, July 20, 1978), p. 49.

III. STATUTORY ANALYSIS

OVERVIEW

The comparative analysis of statutory authorities is a major part of this four-volume study. Despite the many specific variations in the statutory language, certain themes reoccur: risk, benefit, technical, and economic assessments all play important roles in determining regulatory authority to designate and regulate chemicals. Drawing upon the statutory and caselaw reviews, a unique framework for analyzing statutory authority and its components was developed. The analysis covers the key statutory provisions of the laws included in the study. The analysis considers statutory purposes, definitions of hazardous substances, risk definitions, required considerations, and integration directives. Prior to the analysis, it is necessary to first clarify some basic terminology used in this report: the distinction between designation and regulation.

Included Appendix A is a series of "schematic diagrams" of the key statutory provisions analyzed. Symbols in the diagrams represent mandates or authorities, key definitions, and required considerations; the diagrams show the interrelations among the statutory provisions of the different regulatory programs as well as the distinction between designation and regulation.

Because we distinguish designation from regulation, the number of statutory provisions analyzed is quite large. We also analyze a substantial number of topics. This analysis is complicated by the fact that all the statutory provisions of a given law interact to define the bounds of regulatory authority. It is very difficult to say meaningful things about specific aspects of regulatory authority in isolation. Nevertheless, this approach allows for a systematic consideration of the key aspects of regulatory authority when developing integration strategies.

DESIGNATION AND STANDARD-SETTING DISTINGUISHED

At the start, it is important to clarify the use of two key terms "designation" and "regulation." The former should be thought of as a threshold process of identifying hazards that can be distinguished from the crafting of regulatory "standards." Both designation and regulation may be governed by distinct criteria and subject to distinct standards of review.[5] Typically, designation criteria are phrased in terms of risks or potential health effects (i.e., toxicity) presented by a substance. Regulatory criteria are often defined by such terms as "feasibility", "best available technology", "margin of safety", "taking cost into account". In certain instances, different regulatory criteria are established for differing agency actions. For example, the criteria for requiring labeling may be less stringent than the criteria authorizing the ban of a dangerous chemical. The main focus of this study is on the designation of chemical substances as "toxic", "hazardous", or otherwise subject to federal regulation. See Exhibit 2. However, because many laws do not provide distinct designation criteria, this study also analyzes regulatory criteria.

A useful way of understanding the role of designation versus regulation is as follows. Designation may be thought of as the identification of the problem. A chemical exposure may be considered a public health problem if the probability and severity of harm along with the extent of the affected population meet certain criteria. Also, of course, a causal connection between the chemical substance and the harm must be established. Regulation, or standard-setting, may be thought of as the crafting of solutions to the problem. At a minimum, the standard must be effective and may also be subject to cost considerations.

Designation, then, is an essential threshold decision which determines whether a chemical substance (in particular concentrations and amounts) may be subject to further regulatory standards and how the chemical is defined. For example, certain hazardous compounds or isomers may be designated for regulation using any one or more of several different naming conventions. Alternatively, a chemical substance may be designated by being a recognized part of a designated group of chemicals or by meeting the testing criteria of a designated hazard classification (i.e., "flammables", "corrosives"). Finally, only certain concentrations of a substance may be designated or even particle size (e.g., size specifications for asbestos fibres) may serve as a designation parameter.

Either as a separate administrative action or as part of the designation decision, the formulation of standards for designated substances activates control, labelling, or penalty regulations, among others. For example, designated chemicals may be subject to the following kinds of regulatory standards:

- testing requirements
- reporting requirements
- recordkeeping requirements
- liability for clean-up of spills

---

[1] For example, the listing of toxic pollutants under Clean Water Act, Section 307(a)(1), is subject to the "arbitrary and capricious" standard of review but the development of effluent standards for toxic pollutants under Section 307(a)(2) must meet the "substantial evidence" test.

EXHIBIT 2

USE OF DESIGNATION CRITERIA IN CHEMICAL CONTROL STATUTES

Clean Air Act - generally used, Sections 108, 111, 112[a]

Clean Water Act - used, both Section 307 and Section 311

TSCA - not used[b]

RCRA - used, Section 3001

SDWA - used in Section 1412, but permit program used in Section 1421 instead

MPRSA - permit program used instead

FIFRA - permit and classification program used in general

CERCLA - used, Section 102

OSHA - not used

FDA - permit program generally used instead[c]

DOT - classification system used

CPSA - not used

FHSA - mixed case

NRC - permit program used instead

---

[a] Not used in Sections 157, 202, 211, or 231 which authorize or mandate direct regulation without prior designation.

[b] Except for authority to list certain substances, Section 5(b)(4)(A), which has not been exercised, and Section 4(a).

[c] Except for cosmetics, for which premarket approval is not required. Also FDA is required to "list" approved color additives.

- labeling and placarding rules
- use restrictions
- exposure controls in manufacturing
- disposal requirements
- packaging and transportation specifications
- bans
- medical surveillance
- fines and penalties
- emission limits and prohibitions
- ambient concentration standards

Similar requirements may also be imposed under statutes which designate whole classes of substances (e.g., pesticides, drugs, food additives) for regulation, such as FIFRA, MPRSA, and FDCA. These laws require pre-market or pre-disposal approval.

Designation, then, is an inherent part of standard-setting but may also be a separate and independent administrative action. Although the distinction between designation and standard-setting is conceptually straightforward, in practice the distinction is often blurred for a variety of reasons:

(1) Statutes do not consistently separate designation from regulation nor prescribe distinct criteria for each.

(2) Standard-setting criteria (e.g., technological feasibility) may render moot the designation of substances whose control options do not satisfy the criteria.

(3) Judicial review of the authority to designate will generally take into account the regulatory purpose of the designation authority in order to assess the designation decision.

As Exhibit 2 shows, many statutes do NOT contain separate designation criteria. These laws fall into two groups:

(1) Blanket-coverage laws, such as FIFRA, MPRSA (Ocean Dumping Act), and the Food, Drug, and Cosmetic Acts. These laws regulate all substances qualifying as pesticides, materials, and food additives, respectively, and only apply special requirements to a

subset of these substances.[4] These laws treat all covered substances as potentially unsafe until a regulation, permit, or tolerance authorizing use or disposal is promulgated.

(2) Another group of laws uses the "unreasonable risk" concept as a basis for regulation. Here, too, there is no distinct designation phase, but regulation is the exception, not the rule.

Later in this part of the report we discuss the required bases and considerations for making both designation and regulation determinations. Our goal here is to clarify the distinction between these two concepts as a basis for the analytical comparisons which follow. None of the literature reviewed identifies this important distinction or takes it into account when analyzing, for example the role of economic factors in exercising agency authority.

FRAMEWORK FOR ANALYSIS

To provide structure for this analysis, a framework was developed to include the key statutory provisions which together define regulatory authority--for both designation and standard-setting. These include the following:

(1) statutory guidance concerning integration or coordination procedures;

(2) statutory purposes or goals;

(3) definitions of hazardous chemicals included within the jurisdiction of a statute;

(4) distinctive definitions of the risks which are properly addressed by agency regulations; and

(5) required considerations and bases for designation and/or regulation decisions.

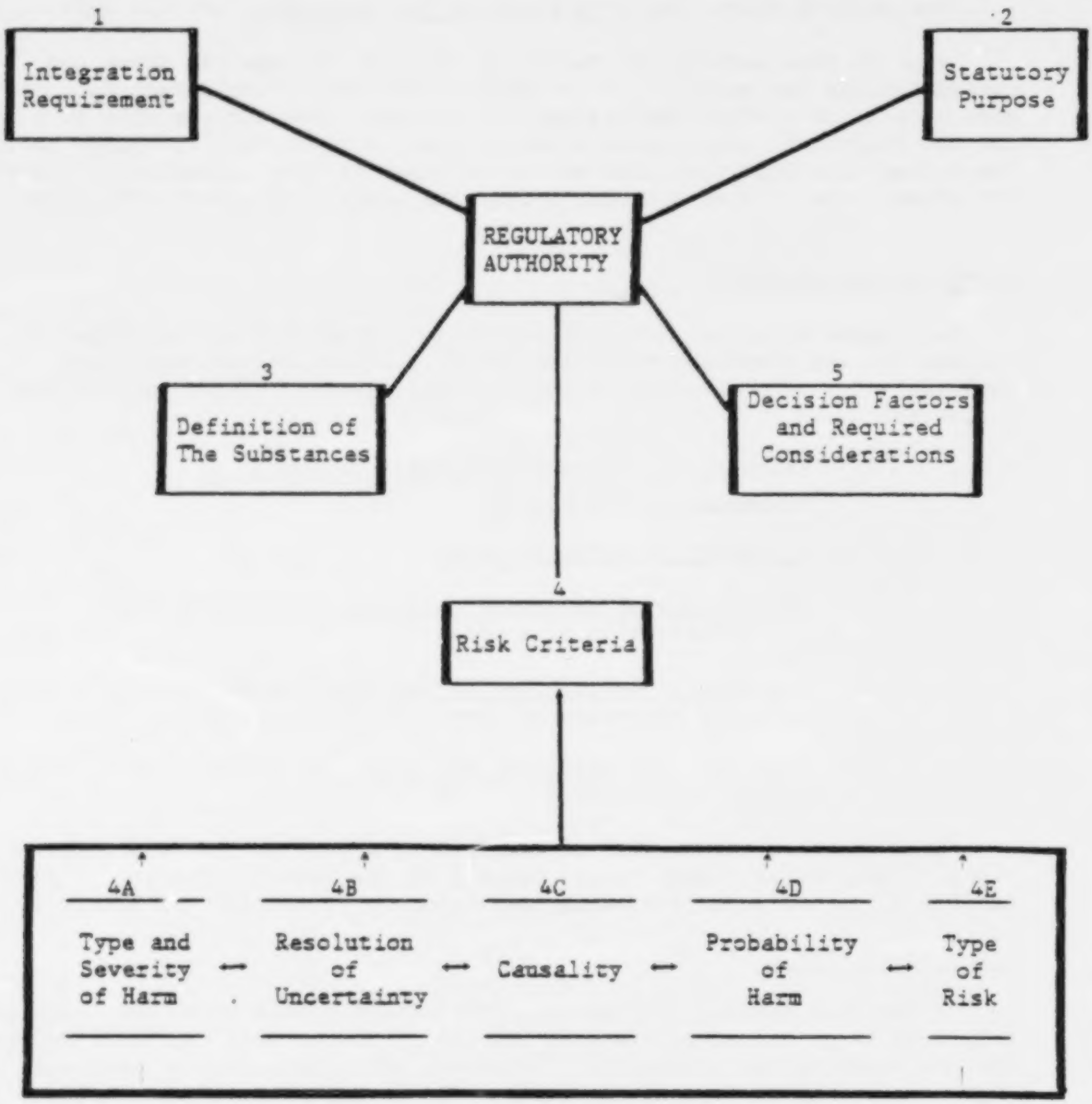
Each of these issues will be analyzed in detail in the following sections. Their relationship to the concept of regulatory authority is shown by Exhibit 3. A court, in reviewing challenged agency actions is likely to

---

[4] For this reason, the chemical designation matrix in Volume 4 includes only substances banned by the FDA, not the thousands that have been approved for use under normal conditions. Likewise, only pesticides or pesticide ingredients subject to special requirements or restrictions are included in the matrix.

EXHIBIT 3

SCHEMATIC OVERVIEW OF STATUTORY FACTORS AFFECTING REGULATORY AUTHORITY


1
Integration Requirement
2
Statutory Purpose
REGULATORY AUTHORITY
3
Definition of The Substances
5
Decision Factors and Required Considerations
4
Risk Criteria
4A
Type and Severity of Harm
4B
Resolution of Uncertainty
4C
Causality
4D
Probability of Harm
4E
Type of Risk

ELEMENTS COMPRISING STATUTORY RISK CRITERIA consider all of these factors, depending on the substantive nature of the case or controversy involved. The numbers in Exhibit 3 indicate the order in which the factors are discussed in the analysis.

INTEGRATION--STATUTORY PROVISIONS REQUIRING CONSISTENCY WITH OTHER STATUTES

This section deals with the major provisions (or lack thereof) in each of the statutes administered by EPA that require consistency and coordination with other statutes. Exhibit 4 summarizes these provisions. The text which follows describes in greater detail how some of these provisions work or were designed to work (or fail to work) in three of these statutes: (1) The Clean Water Act, (2) The Toxic Substances Control Act, and (3) the Resource Conservation and Recovery Act. The regulations reviewed suggest that statutory provisions requiring consistency may play a significant role in regulatory outcomes.

The Clean Water Act (Section 311)

The Clean Water Act (also called the Federal Water Pollution Control Act) requires that regulations issued under Section 311(b) (dealing with discharges of oil or hazardous substances) "be consistent with maritime safety and with marine and navigation laws and regulations and applicable water quality standards." Section 311(b)(3). However, the Act does not address consistency with safety regulations used by DOT for other modes of transport. Although EPA reporting and penalty regulations under this section are triggered only when there actually is a spill during transport, the Department of Transportation (DOT) has continuous jurisdiction over the transportation of hazardous substances. This means that when a spill occurs, both agencies have jurisdiction. Despite this potential for jurisdictional overlap between EPA and DOT in the area of transportation and discharge of hazardous substances, there is no specific mandate in Section 311 that these two agencies work together or issue consistent rules.

In fact, a number of regulatory inconsistencies between EPA and DOT rules in this area have arisen. First, DOT regulations require reporting of discharges only when navigable waters or adjacent shorelines are involved, while EPA requires all spills to be reported, regardless of location. In addition, DOT defines a reportable quantity in terms of the contents of one package or one vehicle; EPA has no such requirements (if several "packages" are discharged, none of which alone is a reportable quantity, but the sum of which is reportable, then reporting is required by EPA but not by DOT). Finally, DOT rules specify that only discharges of substances in certain minimum concentrations of a hazardous chemical are reportable. EPA has no minimum concentration requirements.

EXHIBIT 4

MAJOR STATUTORY PROVISIONS FOR INTEGRATION

FEDERAL WATER POLLUTION CONTROL ACT (FWPCA)--Regulations issued under Section 311 (discharge standards) must "be consistent with maritime safety and with marine and navigation laws and regulations and applicable water quality standards." Section 311(b)(3).

Section 307(k)(1) provides that "[t]he Administrator shall enter into agreements with" the Secretaries of Agriculture, the Army, and the Interior and with other agency heads "to provide for the maximum utilization of other federal laws and programs" to achieve and maintain water quality.

TOXIC SUBSTANCES CONTROL ACT (TSCA)--If both TSCA and other federal laws administered by EPA could be utilized to protect against a particular risk, the Administrator shall act under TSCA only when he determines that it is in the public interest to do so. Sections 6(c)(1), 9(b).

If both TSCA and other federal laws not administered by EPA could be utilized to protect against a particular risk, the Administrator must submit a report about the risk to the agency that administers such other law. If that agency responds by issuing an order stating that the risk described in the report is not actually presented or by initiating, within 90 days, action against such risk, then the Administrator may not take action under Sections 6 or 7 with respect to that risk. Section 9(a).

RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)--RCRA shall not apply to activities or substances subject to the FWPCA, SDWA, MPRSA or Atomic Energy Act except when such application is "not inconsistent with" those Acts. Section 1006(a).

RCRA administration and enforcement shall be integrated with and avoid duplication of the CAA, FWPCA, FIFRA, SDWA, MPRSA, and other Acts administered by EPA. Section 1006(b).

RCRA standards relating to transporters of hazardous waste shall be "consistent" with the Hazardous Materials Transportation Act and shall be promulgated after consultation with the Secretary of Transportation. The Administrator may make recommendations to the Secretary of Transportation concerning regulations under and materials to be covered by that Act. Section 3003.

COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT--If there is a conflict between CERCLA and Section 311 of the FWPCA, CERCLA applies. Section 304(c).

Section 103 is generally not applicable to pesticides registered under FIFRA. Section 103(e). Similarly, Section 103 notification of releases which must be reported and have been reported under RCRA is not required. Section 103(f).

EXHIBIT 4 (continued)

MAJOR STATUTORY PROVISIONS FOR INTEGRATION

The guidelines published pursuant to Section 106 shall be consistent with the national hazardous substance response plan and shall include the assignment of responsibilities and powers authorized by parts of the FWPCA, RCRA, SDWA, CAA, and TSCA. Section 106(c).

SAFE DRINKING WATER ACT (SDWA)--When EPA prescribes interim or revised national primary drinking water regulations, the Food and Drug Administration shall consult with the Administrator and within 180 days, either amend bottled drinking water regulations or publish reasons for not so doing. Section 410, Federal Food, Drug, and Cosmetic Act.

MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT (MPRSA)--"Dumping" does not include (1) certain effluent dispositions regulated under the FWPCA or the Atomic Energy Act; (2) construction or placement on or in water, for a purpos other than disposal, regulated by or pursuant to federal or state laws or programs; and (3) deposits "made for the purpose of developing, maintaining, or harvesting fisheries resources" regulated by or pursuant to federal or state laws or programs. Section 3(f).

CLEAN AIR ACT (CAA)--No major statutory provisions for integration.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)--The Administrator shall consult with "other interested Federal agencies" before establishing procedures and regulations for disposal or storage of pesticides. Section 19(a).

The Administrator shall "provide advice and assistance to the Secretary of Transportation" concerning the transportation of hazardous materials. Section 19(b).

The Administrator shall cooperate with the Department of Agriculture and other agencies in carrying out FIFRA and "securing uniformity of regulations." Section 22(b).

Packaging, container, and wrapping standards "shall be consistent with those established under the authority of the Poison Prevention Packaging Act." Section 25(c).

In Organized Migrants in Community Action vs. Brennan, 520 F.2d 1161 (D.C. Cir. 1975), the court held that, pursuant to FIFRA, EPA, not the Secretary of Labor under the Occupational Safety and Health Act, has authority to provide protection for farm workers from hazards arising from pesticide exposure.

As a result of this, industry remains subject to two sets of conflicting regulations, although EPA has advised DOT that it will not bring actions for failure to report under EPA regulations when such reporting is not required by DOT regulations. As will be seen in the discussion of RCRA below, however, EPA and DOT have been able to work together under that statute; one potential explanation for the problem here is simply that the statute does not require close coordination.

The Toxic Substances Control Act

The Toxic Substances Control Act (TSCA) specifies quite clearly how situations should be handled in which both TSCA and other statutes could be applied to prevent or reduce a particular risk. If the other statutes are administered by EPA, TSCA is to be used only if the Administrator finds that it is "in the public interest" to act under TSCA. Sections 6(c)(1), 9(b). If the other statutes are administered by other agencies, EPA must submit a report to that agency about the risk it perceives. Only if the other agency neither (1) issues an order declaring that the risk is not presented as described in the report, nor (2) initiates action against the risk within 90 days, may the Administrator take action under Sections 6 or 7. Section 9. This same section also clearly sets out that EPA is to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements" on industry.

Several points concerning these provisions are made in the legislative history of TSCA. First, the Administrator's determinations are "discretionary" in both (1) Section 9(a) that a law administered by another agency may prevent or reduce a particular risk and (2) Section 9(b) that the use of TSCA instead of another law administered by EPA is in the public interest. This means that these determinations are not subject to judicial review.[7] Second, in Section 9(a), the other agency need not initiate formal regulatory action within the 90-day period in order to foreclose EPA action, it must only officially initiate action which will "culminate as soon as possible" in regulatory action.[8]

The question which must still be addressed here is how well has this section worked. A single answer can not be given; an answer will be attempted based on a review of chlorofluorocarbons (CFCs) regulations.

---

[7] H.R. Report No. 94-1679, 94th Cong., 2d Sess., 84, 85 (1976). In the second case, this report indicates that even though the Administrator's decision is unreviewable, a reviewing court is expected to require that he examined the other authorities and presented the results of that examination when making his findings. H.R. Report No. 94-1679 at 85.

[8] Ibid.

With respect to CFCs, the initial federal response to the problem, the result of a joint effort of EPA, the Food and Drug Administration, the Consumer Product Safety Commission, and the Department of Commerce, is regarded as a triumph of interagency cooperation. These agencies worked together as the Interagency Work Group on Chlorofluorocarbons in promulgating final rules that eliminated both costly duplication (which could result from having to prepare separate regulations and impact statements) and industry confusion (that may result from different definitions, effective dates, and warning labels). The credit for successful interagency action may, however, not have been due so much to the requirements of the statute as the publicity the issue received, the early contact the agencies made with each other, and their general agreement on a course of action.

The Resource Conservation and Recovery Act

The Resource Conservation and Recovery Act (RCRA) explicitly provides in Section 1006(b) that its administration shall be integrated with and avoid duplication of the CAA, FWPCA, FIFRA, SDWA, MPRSA, and other acts administered by EPA. In Section 1006(a), RCRA also states that it shall not apply to activities or substances subject to the FWPCA, SDWA, MPRSA, or Atomic Energy Act except when such application is "not inconsistent with" those Acts. But the provisions of RCRA that are of greatest interest here are those contained in Section 3003. That section requires that the standards under RCRA relating to transporters of hazardous waste shall be consistent with the Hazardous Materials Transportation Act and shall be promulgated after consultation with the Secretary of Transportation. The Administrator is also authorized to make recommendations to the Secretary of Transportation concerning regulations under and materials to be covered by that Act.

The legislative history indicates that the intent of Congress was to ensure coordination of EPA and DOT actions with respect to the transportation of hazardous materials.[53] This is exactly what has happened. EPA and DOT worked together extensively. Their final rules are interrelated and each set incorporates parts of the rules of the other agency. The two sets of rules are fully interlocking. The entire rule-making process has been coordinated and successful. The congressional intent has been fulfilled.

Conclusion

It is not clear on the basis of these case studies that agencies will cooperate successfully simply because a statute reflects a congressional intent that they coordinate their effort. However, based on the Clean Water Act case study, it does seem reasonable to conclude that the lack of statutorily mandated integration can cause unfortunate results.

---

[53] H.R. Report No. 94-1491 (Part I), 94th Cong., 2nd Sess., 6, 27 (1976), *reprinted in U.S. Code Cong. and Admin. News*, 6238, 6244, 6265 (1976).

ANALYSIS OF STATUTORY PURPOSES

An analysis of statutory authorities for designating chemical substances for government regulation requires a careful assessment of the purposes for which the statutes were developed. The statutory purpose directs the regulatory effort to one or more particular concerns, and sets priorities for the accomplishment of the goals outlined in the statute. Whether the purpose is explicit or implied, it will direct the way in which the statutory mandate is carried out by different agencies. In fact, the differences in statutory purposes are very useful in attempting to understand the differences in the designation of hazardous substances.

Statutory purposes explain dissimilar designations of chemical substances. For example, chemical hazards are addressed differently by the Federal Water Pollution Control Act and the Safe Drinking Water Act. The purpose of the latter is to protect drinking water; one would expect stricter regulations than those for water not directly ingested. Statutory purposes may also be important factors in a court's evaluation of hazardous chemical designations. For example, courts are likely to distinguish between designating chemical substances for the purpose of triggering testing requirements and designating for the purpose of establishing consumer product health standards.

Exhibit 5 presents each purpose relevant to health and safety regulation as it appears in the statute. Not all statutes explicitly state their purpose. In cases when no formal statement of purpose was included in the statute, legislative history and legal decisions were reviewed for statements of congressional intent, purpose, and policy. These statements, as collected in Exhibit 5, easily illustrate the variety of form and content among statutory purposes.

The specificity of statutory purposes varies. Some statutes list the specific methods to be used to achieve their statutory goals. RCRA, for example, specifies how its objectives are to be met as does the OSH Act. Other statutes, such as the HMTA, simply declare a general purpose and do not detail the methods to be used to fulfill it.

Another difference arises in the basic purpose of each act. Of the statutes reviewed, the most salient purpose is to protect human health; protection of the environment also is a prominent purpose. Exhibit 6 illustrates the differences in focus by arranging the statutes into two groups: Those statutes that are intended to protect (1) human health and the environment, and (2) human health only. As would be expected, most of the EPA-related statutes have the dual purpose of protecting human health and the environment.

EXHIBIT 5

STATUTORY PURPOSES

Clean Water Act	Safe Drinking Water Act	RCRA	CERCLA
"The objective of this Act is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters. In order to achieve this objective it is hereby declared that, consistent with the provisions of this Act-- (1) it is national goal that the discharge of pollutants into the navigable waters be eliminated by 1985; (2) it is the national goal that wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water be achieved by July 1, 1983; (3) it is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited;" 33 U.S.C. 1251, Section 101(a)(1)-(3).	No explicit statement of purpose in statute. "The purpose of the legislation is to assure that water supply systems serving the public meet minimum national standards for protection of public health." House Report Number 93-1185, 93rd Congress	"The objectives of this Act are to promote the protection of health and the environment and to conserve valuable material and energy resources by-- ... prohibiting future open dumping on the land and requiring the conversion of existing open dumps to facilities which do not pose a danger to the environment or to health; ... regulating the treatment, storage, transportation, and disposal of hazardous wastes which have adverse effects on health and the environment;" Section 1003	No explicit statement of purpose in statute. "It was the intent of Congress to improve the overall quality of the Nation's environment and to protect the health of our citizens. Today we have the opportunity to pass a bill which focuses on one major environmental danger which has long been neglected. Passage of this measure will establish a Federal mechanism, funded largely through fees on the chemical industry, to respond to the hazards of chemical waste." Congressional Record - Senate 51-5002 - November 24, 1980.

EXHIBIT 5 (continued)

STATUTORY PURPOSES

TSCA	FIFRA	MPRSA	CAA
"It is the policy of the United States that-- (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures; (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and (3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." TSCA-Section 2(b).	No explicit statement of purpose or policy in the statute. "Thus, in examining the EPA decision in this case, the Court must keep in mind that it was the Congressional intent that potentially dangerous pesticides should be removed from the market without delay and that EPA be given expanded authority to regulate pesticides." Dow Chemical Co. v. Blum, 467 F.Supp. 872, 900 (March 1977)	Section 1401(b) declares the Congressional policy "to regulate the dumping of all types of materials into ocean waters and to prevent or strictly limit the dumping into ocean waters of any material which would adversely affect human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities."	"To protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." CAA, Sec. 101(b)(1).

EXHIBIT 5 (continued)

STATUTORY PURPOSES

OSHA

"The Congress declares it to be its purpose and policy ... to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources--

... by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to business affecting interstate commerce;

... by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience; and

... by providing for the development and promulgation of occupational safety and health standards."

Section 2(b).

HMTA

"It is declared to be the policy of Congress in this title to improve the regulatory and enforcement authority of the Secretary of Transportation to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce."

- Section 102

FDA

No explicit statement of purpose in statute.

"[T]he Act's overriding purpose [is] to protect the public health ..."

--Bacto-Unidisk, 394 U.S. at 798 (1968).

--Meserey v. United States, 447 F.Supp. 548, 553 (D.C. Nev. 1977).

The purpose of the new drug provision of the Act is "very clearly, to keep inadequately tested medical and related products which might cause widespread damages to human life out of interstate commerce."

--AMP, Inc. v. Gardner, 389 F.2d 825, 829-830 (2nd Cir. 1968), cert. denied, 393 U.S. 825 (1968), reh. denied, 395 U.S. 917 (1969).

The food additive amendments to the FDCA are "aimed at preventing the addition to the food our people eat of any substance the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability."

- Sen. Rpt. No. 2422, 85th Cong., 2d Sess. (1958), 3 U.S. Code Cong. and Admin. News, p. 5310 (1958).

USCG: Port and Waterways Safety Act

"The Congress finds and declares--

(a) that navigation and vessel safety and protection of the marine environment are matters of major national importance;

(b) that increased vessel traffic in the Nation's ports and waterways creates substantial hazard to life, property, and the marine environment;

(c) that increased supervision of vessel and port operations is necessary in order to--

... reduce the possibility of vessel or cargo loss, or damage to life, property, or the marine environment;

... prevent damage to structures in, on, or immediately adjacent to the navigable waters of the United States or the resources within such waters, and

... insure that the handling of dangerous articles and substances on the structures in, on, or immediately adjacent to the navigable waters of the United States is conducted in accordance with established standards and requirements;"

- Section 2.

EXHIBIT 5 (continued)

STATUTORY PURPOSES

USCG: **Bulk Flammable and Combustible Liquids Act**

"The Congress hereby finds and declares--

... that the carriage by vessels of certain cargoes in bulk or in residue creates substantial hazards to life, property, the navigable waters of the United States (including the quality thereof) and the resources contained therein and to the adjoining land, including but not limited to fish, shellfish, and wildlife, marine and coastal ecosystems, and recreational and scenic values;

... that existing standards for the design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of all such vessels which use any port or place subject to the jurisdiction of the United States or which operate in the navigable waters of the United States must be more stringent and comprehensive for the mitigation of the hazards to life, property, and the marine environment; and

... that standards developed through regulations shall incorporate the best available technology and shall be required unless clearly shown to create an undue economic impact which is not outweighed by the benefits to navigation and vessel safety or protection of the marine environment."

- Section 391(a).

Atomic Energy Act

"It is therefore declared to be the policy of the United States that--

(a) the development, use, and control of atomic energy shall be directed so as to make the maximum contribution to the general welfare, subject at all times to the paramount objective of making the maximum contribution to the common defense and security; and

(b) the development, use, and control of atomic energy shall be directed so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise."

- Section 2011.

It is the purpose of this chapter to effectuate the policies set forth above by providing for--

a program to encourage widespread participation in the development and utilization of atomic energy for peaceful purposes to the maximum extent consistent with the common defense and security and with the health and safety of the public.

- Section 2013.

USDA: **Wholesome Meat Act**
Wholesome Poultry Act,
and Egg Products
Inspection Act

to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

- Sections 602, 451, and 1031, respectively.

Wholesome Poultry Act

"to prevent the movement or sale in interstate or foreign commerce of, or the burdening of such commerce by, poultry products which are adulterated or misbranded."

- Section 452.

Egg Product Inspection Act

"to prevent the movement or sale for human food, of eggs and egg products which are adulterated or misbranded or otherwise in violation of this chapter."

- Section 1032.

CPSA

"The purposes of this Act are--

(1) to protect the public against unreasonable risks of injury associated with consumer products,..."

-Section 2(b).

EXHIBIT 5 (continued)

STATUTORY PURPOSES

FHSA	PPPA		
No explicit statement of purpose in the statute. The purpose of this bill is to provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use. --H.R. Rep. No. 1861, 86th Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 2833, 2834 (1960). The purpose of the 1966 Amendment to the Act was: [T]o ban the sale of toys and other children's articles containing hazardous substances; to authorize the Secretary of Health, Education, and Welfare to ban the sale of other substances which are so hazardous in nature that they cannot be made suitable for use in or around the household by cautionary labeling; to extend coverage of the Hazardous Substances Labeling Act to unpackaged as well as packaged hazardous substances intended for household use; and to make it clear that household products treated with pesticides are not exempt from that act. --H.R. Rep. No. 2166, 89th Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 4095 (1966).	No explicit statement of purpose or policy in the statute. The purpose of this Act was to provide for "special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances." --H.R. Rep. No. 91-1642, 91st Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 5326, 5327 (1970).		

EXHIBIT 6

CLASSIFICATION OF STATUTORY PURPOSES

Human Health and the Environment	Human Health Only
RCRA	SDWA[a]
CERCLA[a]	HMTA[b]
TSCA	OSHA
FIFRA[a]	FDA[a]
CWA	AEA[b]
MPRSA	USDA Laws
CAA[b]	CPSC Laws
USCG Laws[b]	

---

[a] The purpose is not explicitly stated in the statute. It is found in the legislative history.

[b] These statutes are also intended to protect against risks to property. Regulations issued under HMTA do address environmental as well as health and property hazards.

In particular, note the differences among the core purposes of the EPA statutes:

CWA	Restore and Maintain Integrity of the Nation's Waters
SDWA	Protect Public Health
RCRA	Protect Health and the Environment
CERCLA	Protect Human Health and Improve the Environment
TSCA	Protect Human Health and the Environment
FIFRA	Protect Public Health and the Environment
MPRSA	[Protect] Human Health, Welfare, or the Marine Environment
CAA	Protect and Enhance the Quality of the Nation's Air

The terms "restore", "improve", and "enhance" used in the CWA, CERCLA, and CAA imply a more active government role than the term "protect". However, the other laws often have extensive control powers--such as the permit system required under the MPRSA. In addition, the Clean Air Act concern with air quality is conditioned by the goal of promoting the public health and welfare. Of course, the statutory purpose forms just one element in the analysis of regulatory authority--other statutory provisions will be involved.

In a landmark Clean Air Act case, concerning the legality of regulations allowing companies to "bubble" out of new source performance standards, the D.C. Circuit Court of Appeals rested its holding, in part, on the fact that "bubbles" do nothing to improve air quality (but do cut costs) and cited the goal of the Clean Air Act to "enhance" air quality, not merely to "maintain" it.[103]

The non-EPA statutes primarily address the protection of public health (FDA, USDA, and CPSC laws). The OSHA Act's purpose as to "assure" "safe and healthful working conditions" "so far as possible". The Atomic Energy Act seeks to "maximize" the contribution of atomic energy to the general welfare consistent with the health and safety of the public. The DOT laws, finally, give much attention to the protection of property; some of the Coast Guard's laws also address the protection of the environment.

---

[103] ASARCO, Inc. v. EPA, 11 ERC 1129, 1135; 578 F.2d 319 (D.C. Cir. 1978).

Note that the HMTA does not explicitly mention any concern with the environment, per se. Only hazards to life and property are referenced. This is also the case with the AEA, which nowhere mentions the environment.

- It has been argued, for example, that DOT has no authority under the HMTA to regulate hazardous materials that pose only environmental risks. DOT took the opposite position in its rulemakings adopting hazardous substances and wastes designated by the EPA pursuant to CWA and RCRA. Because the environment mediates many toxic exposures, an agency cannot protect human health without controlling the presence of toxics in the environment. But materials toxic only to fish or wildlife and not humans, on the other hand, would not seem to fall under the ambit of the HMTA unless they also constituted someone's property (e.g., privately owned oyster beds). There has been no judicial test of DOT's authority to resolve this issue.

Some provisions are more specific than others in their descriptions of health related purposes. TSCA, RCRA, and MPRSA, for example, define the types of health effects to be prevented, i.e., "unreasonable risk of injury", "adverse effects". At the other extreme is the Clean Air Act which generally states as its goal "to protect the public health . . ." Likewise, the Clean Water Act merely implies that one of its purposes is to protect human health by stating: "It is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited." Prohibiting the discharge of toxic pollutants will reduce human exposure to toxics in the water, and presumably, protect human health. These issues are discussed in more detail in later sections of the analysis dealing with statutory risk criteria.

Besides public health, economic issues are often addressed in the statutory purpose. Some of the statutes aim to favorably affect the economy. An example is the Atomic Energy Act which, (among other things), purports "to strengthen free competition in private enterprise" (emphasis added). Other statutes are designed so that actions under the statute will avoid aggravating or damaging the economy, including adverse effects on economic potentialities (MPRSA), human resources (OSHA), or the economic benefits of the use of a pesticide (FIFRA). Economic considerations invariably are part of the regulatory process to one degree or another, whether they are mentioned as a statutory purpose or not. Usually, economic factors enter either as part of the definition of the risk (e.g., unreasonable risk) or as a required consideration in promulgating a standard. These issues will be addressed later.[11]

---

[11] We do not discuss the status and requirements of Executive Order 12291 which requires certain economic analyses.

A statutory factor closely related to the "purpose" is the definition of those substances subject to regulation. This is reviewed next.

ANALYSIS OF STATUTORY DEFINITIONS OF HARMFUL SUBSTANCES

One of the key factors shaping the regulatory authority of a statute is the definition of those substances subject to designation and/or regulation. Agency authority is effectively circumscribed by these definitions.

Exhibit 7 lists the definitions included in the statutes reviewed. The Exhibit focuses on definitions of harmful substances, where this is provided (e.g., the RCRA definition of hazardous wastes). Where a separate category is not included in the statute, the Exhibit shows the definitions of the general category of substances subject to regulation (e.g., "materials" under MPRSA, "pesticides" under FIFRA). In the latter case, the statutes typically include other provisions tying designation and regulation to some definition of harm to be avoided.

The statutes containing definitions of "harmful" substances use a variety of descriptive terms such as:

- "pollutants"................FWPCA §502(6)
- "toxic pollutant"...........FWPCA §502(13)
- "hazardous substance".......FWPCA §311(b)(2)(A)
- "contaminant"...............SDWA §1401(6)
- "hazardous waste"...........RCRA §3001
- "hazardous air pollutant"...CAA §112(a)(1)
- "air pollutant".............CAA §302(g)
- "hazardous substance".......CERCLA §101(14)
- "pollutant or contaminant"..CERCLA §104(a)(2)
- "hazardous materials".......HMTA §103(2)
- "hazardous material"........BFCLA[12] 49 USC §4417(a)(2)(C)
- "hazardous substance".......FHSA §2(f)(1)

The most popular terms are "hazardous substance" (defined differently in CWA §311, CERCLA §101(14), and FHSA §2(f)(1), "hazardous material," and "contaminants." The use of the term "hazardous substance" by CERCLA is most unfortunate since it includes CWA §311 "hazardous substances" as well as other substances. Rules adopted by DOT to incorporate §311 "hazardous substances" as DOT "hazardous materials" further complicate the lexicon.

It should be noted that the Toxic Substance Control Act does not define or otherwise use the term "toxic substances". Rather, TSCA defines "chemical substances" and "mixtures" which are subject to regulation if certain harm criteria are met. Likewise, neither FIFRA nor the MPRSA specify a category of harmful substances; FIFRA defines "pesticides" which are all subject to regulation as does MPRSA with "materials".

---

[12] Bulk Flammable and Combustible Liquids Act (U.S. Coast Guard).

EXHIBIT 7

STATUTORY DEFINITION OF HARMFUL SUBSTANCES--EPA

TSCA	FWPCA	SDWA
"Chemical substance" (§3(2)). any organic or inorganic substance of a particular molecular identity, including-- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical. (B) Such term does not include-- (i) any mixture, (ii) any pesticide (as defined in FIFRA) when manufactured, processed, or distributed in commerce for use as a pesticide. (iii) any source material, special nuclear material, or byproduct in the Atomic Energy Act of 1954 and regulations issued under such Act), (iv) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the FDCA) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. "Mixture" (§3(8)). any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.	"Pollutants" (§502(6)). dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal and agricultural waste discarded into the water. "Toxic pollutants" (§502(13)). those pollutants, or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingesting through food chains, will, on the basis of information available to the Administrator cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations in such organisms or their offspring. "Hazardous substance" (§311(b)(2)(A)). when discharged in any quantity presents an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	"Contaminant" (§1401(6)). any physical, chemical, biological, or radiological substance or matter in water.

EXHIBIT 7 (continued)

STATUTORY DEFINITION OF HARMFUL SUBSTANCES--EPA

MPRSA	RCRA	FIFRA
"Material" (§103(c)). matter of any kind or description, including, but not limited to, dredge material, solid waste, incinerator residue, garbage, sewage, sewage sludge, munitions, radiological, chemical, and biological warfare agents, radioactive materials, chemicals, biological and laboratory waste, wreck or discarded equipment, rock, sand, excavation debris, and industrial, municipal, agricultural and other waste; but such term does not mean sewage from vessels within the meaning of section 312 of the Federal Water Pollution Control Act, as amended (33 USC 1322). Oil within the meaning of section 311 of the Federal Water Pollution Control Act, as amended (33 USC 1321), shall be included only to the extent that such oil is taken on board a vessel or aircraft for the purpose of dumping.	"Hazardous wastes" (§1004(5)). any waste or combination of wastes which, because of its quantity, concentration, or physical, chemical, or infectious characteristics may (i) cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or (ii) pose a substantial present or potential hazard to human health or the environment when it is improperly treated, stored, transported, disposed of or otherwise managed.	"Pesticide" (§2(v)). (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or dessicant: Provided, That the term "pesticide" shall not include any article (1)(a) that is a "new animal drug" within the meaning of section 201(w) of the FDCA, or (b) that has been determined by FDA not to be a new animal drug by a regulation establishing conditions of use for the article, or (2) that is an animal feed within the meaning of section 201(x) of the FDCA bearing or containing an article covered by clause (1) of this provision.

EXHIBIT 7 (continued)

STATUTORY DEFINITION OF HARMFUL SUBSTANCES--EPA

CAA	CERCLA (Superfund)
"Air pollutant" (§302(g)). any air pollution agent of combination of such agents, including any physical, chemical, biological, radioactive (including source material, special nuclear material, and by product material) substance or matter which is emitted into or otherwise enters the ambient air. "Hazardous air pollutant" (§112(a)(1)). an air pollutant to which no ambient air quality standard is applicable and which in the judgment of the Administrator causes, or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness.	"Hazardous substance" (§101(14)). (A) any substance designated pursuant to section 311(b)(2)(A) of the Clean Water Act (FWPCA). (B) any element, compound, mixture, solution or substance designated pursuant to section 102 of this Act (shown below). (C) any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act (but not including any waste the regulation of which under the Solid Waste Disposal Act has been suspended by Act of Congress), (D) any toxic pollutant listed under section 307(a) of the FWPCA (E) any hazardous air pollutant listed under section 112 of the CAA, and (F) any imminently hazardous chemical substance or mixture with respect ot [sic] which the Administrator has taken action pursuant to section 7 of the TSCA. The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under subparagraphs (A) through (F) of this paragraph, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). §102(a). The Administrator shall promulgate and revise as may be appropriate, regulations designating as hazardous substances, in addition to those referred to in section 101(14) of this title, such elements, compounds, mixtures, solutions, and substances which, when released into the environment may present substantial danger to the public health or welfare or the environment. "Pollutant or contaminant" (§104(a)(2)). shall include, but not be limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.

EXHIBIT 7

STATUTORY DEFINITION OF HARMFUL SUBSTANCES--NON-EPA

NRC	DOT/USCG	FDA
The Atomic Energy Act "byproduct material" (§11(e)). any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. "source material" (§11(z)) (1) uranium, thorium, or any other material which is determined by the Commission pursuant to the provisions of §61 of this title to be source material; or (2) ores containing one or more of the foregoing materials, in such concentration as the Commission may by regulation determine from time to time. "special nuclear material" (§11(aa)). (1) plutonium, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of §51 of this title, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material.	Hazardous Materials Transportation Act "Hazardous materials" (§103(2)). a substance or material in a quantity and form which may pose an unreasonable risk to health and safety or property when transported in commerce. Dangerous Cargo Act No hazardous substance definition. However, the DCA does define "Combustible liquid." Bulk Flammable and Combustible Liquids Act "Hazardous material" (§4417(a)(2)(c)). any liquid material or substance which is (i) flammable or combustible; or (ii) designated a hazardous substance under section 311(b) of the FWPCA, as amended; or (iii) designated a hazardous material under section 104 of the HMTA. Ports and Waterways Safety Act No hazardous substance definition. 33 U.S.C. §1225(a)(2)(A) does reference the definition of hazardous material contained in the BFCLA.	Food, Drug and Cosmetic Act (§402). A food is considered "adulterated": (a)(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (a)(2)(A) if it bears or contains any added poisonous or deleterious substance which is unsafe within the meaning of section 406; or (a)(2)(B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (a)(2)(C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such residue has been removed to the extent possible in good manufacturing practice and the concentration does not exceed the prescribed tolerance; or (a)(2)(D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512; or (C) if it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a); or (a)(3)(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

EXHIBIT 7 (continued)

STATUTORY DEFINITION OF HARMFUL SUBSTANCES--NON-EPA

USDA	OSHA	CPSC
Wholesome Meat Act (§1(j)) Wholesome Poultry Act (§4(e)) Egg Products Inspection Act (§4) A meat, poultry, or egg product is "adulterated" if: (1) it bears or contains may poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health; (2) it bears or contains any added poisonous or added deleterious substance; (3) it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of the FDCA; (4) it bears or contains any food additive which is unsafe within the meaning of the FDCA; (5) it bears or contains any color additive which is unsafe within the meaning of the FDCA, Provided, That an article which is not otherwise deemed adulterated under clause the FDCA shall nevertheless be deemed adulterated of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in official establishments. . . . (6) it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to the FDCA (WMA section 1(j), WPA section 4(e), EPIA section 4).	The term "toxic material" is used in §6(b)(5) but is not defined in the Act.	Federal Hazardous Substances Act "Hazardous substance" (§2(f)(1)) Any substance or mixture of substances which: (1) is toxic, corrosive, an irritant, a strong sensitizer, flammable, combustible, or generates pressure through decomposition, heat, or other means; or (2) causes substantial personal injury or illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children; or (3) is a radioactive substance that requires labeling to protect the public health; or (4) is a toy or other article which presents an electrical, mechanical, or thermal hazard. However, the term shall not apply to (1) economic poisons subject to the FIFRA, nor to foods, drugs, and cosmetics subject to the FDCA, nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house, but such term shall apply to any article which is not itself an economic poison within the meaning of the FIFRA but which is a hazardous substance by reason of bearing or containing such an economic poison; or (2) any source material, special nuclear material, or byproduct material as defined in the AEA. Poison Prevention Packaging Act (§2(2)) CPSC may require "special packaging" standards for any "household substance" which is also: (§2(2))--cont'd. (A) a hazardous substance under the Federal Hazardous Substances Act (toxic, corrosive, irritant, strong sensitizer, or substance which generates pressure); (B) a food, drug, or cosmetic according to the FDCA; or (C) a fuel stored in a portable container used for heating, cooking, or refrigerating in the home; (D) an "economic poison" as defined in the Federal Insecticide, Fungicide, and Rodenticide Act. Consumer Product Safety Act "Consumer product" (§3(a)(1)). any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include-- (A) any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer, (B) economic poisons (as defined by the FIFRA), (C) drugs, devices, or cosmetics (as such terms are defined in sections 201(h), (h), and (i) of the FDCA), or (D) food. The term "food," as used in this subparagraph means all "food," as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act, including poultry and poultry products (as defined in sections 4(e) and (f) of the Poultry Products Inspection Act), meat, meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

The Occupational Safety and Health Act uses the term "toxic materials" in §6(b)(5) but does not define that term. The USDA and FDA statutes provide definitions of "adulterated" or "unsafe" products but do not define such key terms as "poisonous or deleterious substances". Finally, the Consumer Product Safety Act only defines consumer products.

DEFINITION OF THE RISK

After reviewing both the statutory authorities and the case law which attempt to interpret these difficult provisions, there are five potential, distinct aspects to a statutory definition of risk:

(1) type (or magnitude) of harm involved;

(2) degree of certainty required;

(3) the required causal connection between the substance, regulation, and the harm;

(4) the probability of the harm (i.e., magnitude of the risk), and

(5) the type of risk subject to control (e.g., unreasonable risk).

Not every statute incorporates all of these aspects. And the terms used tend to overlap and be ambiguous, at times. (See Exhibit 8 where the key terms are divided into three columns.) This will become clearer in the following discussion. Distinguishing these aspects for the purpose of comparative analysis is an exercise in semantics and legal interpretation that may appear confusing. However, statutory inconsistencies in defining risks prevent a simpler approach.

Before proceeding further, a short example may be helpful. Under section 211 of the Clean Air Act, fuels and fuel additives can be regulated whose emission products

(1) cause or contribute to air pollution which
(2) may reasonably be anticipated to
(3) endanger
(4) public health or welfare.

The phrase "cause or contribute" relates to the causal role or connection which must be shown between the pollutant and the harm. The phrase "may reasonably be anticipated" refers to the degree of certainty required. The term "endanger" describes the risk, particularly the magnitude of the risk.[13/] The harm, presumably, is danger to the public health or welfare.

[13/] Risk = (probably of harm) x (magnitude of harm).

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION

Statutory Provision	Mandate or Authority	Rationale for Designation/Regulation Certainty/Causality/Probability	Type of Risk	Type of Harm
TSCA §4(a)(1)	EPA "may" issue a testing standard if a chemical substance or mixture	(A) "may present" OR	"an unreasonable risk of"	"injury to health or the environment"
		(B) "is or will be" produced in substantial quantities and (i) "enters or may reasonably be anticipated to enter" OR		"the environment in substantial quantities"
		(ii) "there is or may be"		"significant or substantial human exposure"
TSCA §4(f)	EPA must "find" that the risk is "not unreasonable" or initiate action under §§ 5, 6, or 7, if	"there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present"	"a significant risk" of	"serious, widespread harm to human beings from cancer, gene mutations, or birth defects"
TSCA §5(b)(4)(A)	EPA "may" compile and keep current a list of chemical substances that	"presents or may present"	"an unreasonable risk of"	"injury to health or the environment"
TSCA §5(f) [§6(a)]	EPA "shall" issue a rule to limit or prohibit [for §6(a)] the use of a chemical substance [or mixture] if	"there is a reasonable basis to conclude" that it "presents or will present"	"an unreasonable risk of"	"injury to health or the environment"
CWA §311(b)(2)(A)	EPA "shall" designate "elements and compounds which"	"present"	"an imminent and substantial danger"	"danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches"
CWA §311(b)(4)	EPA "shall" designate "those quantities of 'hazardous substances' the discharge of which"	"may be"	"harmful to"	"the public health or welfare of the United States, including, but not limited to fish, shellfish, wildlife, and public and private property, shorelines and beaches."

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

		Rationale for Designation/Regulation		
Statutory Provision	Mandate or Authority	Certainty/Causality/Probability	Type of Risk	Type of Harm
CWA §307(a)	EPA "may" revise list of designated toxic pollutants to include substances which	"will cause"	--	"death, disease, behavioral abnormalities, cancer, mutations, physiological malfunctions including malfunctions in reproduction, or physical deformations in organisms or their offspring"
SDWA §1401(1)	EPA "may" revise and "must" issue primary drinking water regulations for contaminants which	"may have"	--	"any adverse effect on the health of persons"
SDWA §1412(b)(1)(B)	EPA "shall" by rule establish maximum levels for each contaminant which	"may have"	--	"any adverse effect on the health of persons"
SDWA §1421(a)(1), (d)	EPA "shall" publish regulations for underground injection control if			
	such injection	"may" result in	--	"the presence of any contaminant"
	and			
	if the presence of such contaminant	"may affect adversely"		"the health of persons"
MPRSA §102(a)	Dumping permits "may" be issued where dumping	"will not"	"unreasonably degrade or endanger"	"degrade or endanger human health, welfare, or amenities, or the marine environment,-ecological systems, or economic potentialities"

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Mandate or Authority	Rationale for Designation/Regulation		
		Certainty/Causality/Probability	Type of Risk	Type of Harm
RCRA §3001, §3004(5)	EPA "shall" promulgate criteria and regulations identifying the characteristics of hazardous wastes and listing particular hazardous wastes which	(A) "may cause or contribute to"	"an increase in"	"mortality" or "serious irreversible, or incapacitating reversible, illness"
		OR		
		(B) "may pose" [when "improperly" managed]	"a substantial present or potential hazard to"	"human health or the environment"
RCRA §3002, §3003, §3004	EPA "shall" promulgate regulations applicable to generators, transporters, and owners or operators of facilities for listed or identified hazardous wastes as	"may be necessary to protect"	--	"human health and the environment"
FIFRA §3(c)(5)(C)	EPA "shall" register a pesticide if	(C) "[it] will perform its intended function without" [and (D)] "will not generally cause" ["when used in accordance with widespread and commonly recognized practice" or as directed]	--	"unreasonable adverse effects on the environment"
FIFRA §3(c)(7)(A)(ii)	EPA "may" conditionally register or amend registration if that	"would not significantly increase"	"the risk of"	"unreasonable adverse effects on the environment"
FIFRA §3(c)(7)(B)(ii)	EPA "may" conditionally amend registration to permit additional uses of a restricted pesticide if that	"would not significantly increase"	"the risk of"	"any unreasonable adverse effects on the environment"
FIFRA §3(c)(7)(C)	EPA "may" conditionally register a pesticide containing any unregistered active ingredient if its use	"will not cause"	--	"any unreasonable adverse effects on the environment"

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

		Rationale for Designation/Regulation		
Statutory Provision	Mandate or Authority	Certainty/Causality/Probability	Type of Risk	Type of Harm
FIFRA §3(d)(1)(C)	EPA "shall" restrict the uses of a pesticide if, otherwise, its use	"may generally cause" ["when used in accordance with widespread and commonly recognized practice" or as directed]	--	"unreasonable adverse effects on the environment, including injury to the applicator"
FIFRA §3(d)(1)(D)	EPA "shall" classify a pesticide for general use if its use	"will not generally cause" [same condition as above]	--	"unreasonable adverse effects on the environment"
FIFRA §6(b)	EPA "may" commence proceedings to cancel or change the classification of a pesticide if its use	"generally causes" [same condition as above]	--	"unreasonable adverse effects on the environment"
FIFRA §25(c)(3)	EPA "may" establish packaging standards	"in order to protect children and adults"	--	"[against] serious injury or illness resulting from accidental ingestion or contact"
CAA §108(a)(1)	EPA "shall" list each air pollutant which	"causes or contributes to air pollution which may reasonably be anticipated to"	"endanger public health or welfare"	--
CAA §109	EPA "shall" establish air quality standards which	"are requisite to protect the public health"	--	--
CAA §111(b)(1)(A)	EPA "shall" list a category of new sources of pollution if it	"causes, or contributes signficantly to, air pollution which may reasonably be anticipated to"	"endanger public health or welfare"	--
CAA §112	EPA "shall" list as a "hazardous air pollutant" any air pollutant which	"may reasonably be anticipated to result in"	"an increase in"	"mortality or serious irreversible, or incapacitating reversible, illness."
CAA §157(b)	EPA "shall" regulate "any substance, practice, process, or activity" which	"may reasonably be anticipated to affect the stratosphere, especially ozone, if such effect" "may reasonably be anticipated to"	"endanger public health or welfare"	--

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Mandate or Authority	Rationale for Designation/Regulation		
		Certainty/Causality/Probability	Type of Risk	Type of Harm
CAA §202(a)	EPA "shall" regulate any air emissions from new motor vehicles and engines which	"cause, or contribute to, air pollution which may reasonably be anticipated to"	"endanger public health or welfare"	--
CAA §211	EPA "may" control or prohibit the manufacture, sale, or use of a fuel or fuel additive if any emission product	"causes or contributes to air pollution which may reasonably be anticipated to"	"endanger the public health or welfare"	--
CAA §231	EPA "shall" issue standards for any aircraft emission which	"causes, or contributes to, air pollution which may reasonably be anticipated to"	"endanger public health or welfare"	--
CERCLA §102	EPA "shall" designate as "hazardous substances" "such elements, compounds, mixtures, solutions, and substances which"	"may present" ["when released into the environment"]	"substantial danger to the public health or welfare or the environment"	--
CERCLA §104(a)(2)	The phrase "pollutant or contaminant" "shall include, but not be limited to, any element, substance, compound, or mixture, including disease-producing agents, which"	"will or may reasonably be anticipated to cause" ["directly...or indirectly" after "release into the environment"]	--	"death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunction (including malfunctions in reproduction)" in "organisms or their offspring"
OSHA §6(b)(5) 29 U.S.C. §655(b)(5)	OSHA "may" promulgate standards dealing with "toxic materials" which	"most adequately assures" that	"to the extent feasible"	"[no employee will suffer] material impairment of health or functional capacity"
OSHA §3(8)	An OSHA standard means one whose requirements are	"reasonably necessary or appropriate to provide safe or healthful employment and places of employment"	--	--

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Mandate or Authority	Rationale for Designation/Regulation		
		Certainty/Causality/Probability	Type of Risk	Type of Harm
HMTA §104	DOT "shall" designate "such quantity and form of material or group or class of materials" as a "hazardous material" that	"may pose"	"an unreasonable risk to health and safety or property"	--
HMTA §105	DOT "may" issue regulations for the safe transport in commerce of hazardous materials as are	"necessary or appropriate"	--	--
PWSA 33 U.S.C. §1225	DOT/USCG "may" take such action as is	"necessary to"		(1) "prevent damage to, or the destruction of, any bridge...." (2) "protect the navigable waters and the resources therein from harm"
BWCLA 33 U.S.C. §391a(6)(A)	DOT/USCG "shall" issue regulations as	"may be necessary for increased protection against hazards to life and property, ... and for enhanced protection of the marine environment"	--	--
DCA 46 U.S.C. §170	DOT/USCG "shall" "define, describe, name, and classify all explosives or other dangerous articles or substances" and "shall" establish such regulations as	"may be necessary"	--	--
FDCA §406 21 U.S.C. §346	FDA "shall" promulgate regulations establishing tolerances for [unavoidable or required] poisonous or deleterious substances in food	"necessary for the protection of public health"	--	--

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Mandate or Authority	Rationale for Designation/Regulation		
		Certainty/Causality/Probability	Type of Risk	Type of Harm
FDCA §408 21 U.S.C. §346a	FDA "shall" promulgate regulations establishing tolerances for pesticide residues on raw agricultural commodities	"necessary to protect the public health"	--	--
FDCA §409 21 U.S.C. §348	FDA "shall" promulgate regulations establishing tolerances for the safe use of food "additives" in food if	"required in order to assure that the proposed use of an additive will be safe"	--	--
FDCA §409(c) 21 U.S.C. §348(c)	No food additive "shall" be deemed to be safe if it is found to	"induce" [when ingested by man or animal] (This is the famous Delaney Clause)	--	"cancer in man or animal" unless, for use on animal feed only, "no residue of the additive will be found" in any edible portion of, or food yielded from, consuming animals
FDCA §505 21 U.S.C. §355(c); (d)(2); (e)(1),(2)	FDA "shall" deny a new drug application or withdraw approval if ... such new drug	"is unsafe" or "is [not] safe" for intended use	--	--
FDCA §512 21 U.S.C. §360b(d), (e), (m)	FDA "shall" refuse to approve or shall withdraw approval of a new animal drug or feed containing such drug if it	"(2) is unsafe" or "is [not] safe" for intended use, or	--	--
		"(B) induces" [when ingested by man or animal]		"cancer in man or animal" unless "(ii) no residue . . . will be found" in any edible portions of, or food yielded from, such animals

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Mandate or Authority	Rationale for Designation/Regulation		
		Certainty/Causality/Probability	Type of Risk	Type of Harm
FDCA §402(a)(1) 21 U.S.C. §342(a)(1)	Food "shall" be deemed adulterated which bears or contains any [avoidable or unnecessary] poisonous or deleterious substance which	"may render" it	--	"injurious to health"
	but in case the substance is not an added substance, food shall only be deemed adulterated if the substance	"ordinarily render[s]" it	--	"injurious to health"
FDCA §706(b)(1) 21 U.S.C. §376(b)(1)	FDA "shall" by regulation, provide for "separately listing color additives" for specific uses in or on food, drugs, devices, and cosmetics, if such additives	"are safe" or "will be safe"	--	--
FDCA §706(b)(5)(B) 21 U.S.C. §376(b)(5)(B)	FDA "shall not list a color additive" for any use if the additive	"induce[s]"	--	"cancer in man or animal" unless, for color additives used in feed, "no residue of the additive will be found" in any edible portion of, or food yielded from, animals consuming the feed
FDCA §601 21 U.S.C. §361	A cosmetic "shall" be deemed adulterated if "(1) [it] bears or contains any poisonous or deleterious substance which" or	"may render it"	--	"injurious to users"
	"(4) [its] container is composed, in whole or in part, of any poisonous or deleterious substance which"	"may render the contents"	--	"injurious to health"

EXHIBIT 8

RISK RATIONALE FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Mandate or Authority	Rationale for Designation/Regulation		
		Certainty/Causality/Probability	Type of Risk	Type of Harm
CPSA §7 15 U.S.C. §2056	CPSC "may" promulgate consumer product safety standards if	a safety standard is "reasonably necessary to eliminate or reduce"	an "unreasonable risk" of	"injury" (i.e., "death, personal injury, or serious or frequent illness")
CPSA §8 15 U.S.C. §2057	CPSC "may" ban a hazardous product if	(1) it "presents"	an "unreasonable risk" of	"injury" (i.e., "death, personal injury, or serious or frequent illness")
		AND		
		(2) no "feasible" safety standard "would adequately protect" the public from	the associated unreasonable risk of	"injury" (i.e., "death, personal injury, or serious or frequent illness")
FHSA §2(f)(1)(A), §3(a) 15 U.S.C. §1261(f)(1)(A), §1262(a)	CPSC "may" declare a substance or mixture "hazardous" if	it "may cause" [during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children]	--	"substantial personal injury or substantial illness"
FHSA §3(b) 15 U.S.C. §1262(b)	CPSC "may" establish special labeling requirements if	"necessary for the protection of the public health and safety"	"in view of the special hazard presented"	--
FHSA §2(q) 15 U.S.C. §1261(q)	CPSC [may] classify substances as banned if	"protection of the public health and safety can be adequately served only by" such a ban	"the degree and nature of the hazard involved" renders cautionary labeling inadequate	--
PPPA §3 15 U.S.C. §1472	CPSC "may" establish special packaging standards if	"required to protect children"	"the degree and nature of the hazard to children" requires special packaging	"serious personal injury or serious illness resulting from handling, using, or ingesting" hazardous substances
FFA §4 15 U.S.C. §1193	CPSC "shall" institute proceedings for determining flammability standards if	a regulation "may be [or "is"] needed to ["adequately"] protect the public against"	"unreasonable risk" of	"fire leading to death or personal injury, or significant property damage"

A different approach is taken for toxic effluents under the Clean Water Act, Section 307(a). There, EPA is authorized to regulate pollutants which "will" (not may) "cause" enumerated harms (death, disease, etc.) on the basis of available information. This formulation seems to require a stronger causal connection between pollution and harm than the Clean Air Act approach, and seems to allow less subjectivity than the "may reasonably be anticipated" formulation.[14]

In the following pages we analyze the statutory language relating to these issues. As shown by Exhibit 8, statutory language may be divided into three categories. Therefore, the analysis consists of three parts:

(1) Type of harm involved, which is more or less explicitly described in the statute and/or subsumed under risk terms;

(2) Type of risk involved, which includes both the magnitude (i.e., probability) of the risk as well as the type of risk subject to control (e.g., unreasonable risk);

(3) Required nexus or connection between the substance, regulation, and the harm or risk involved, which is described by statutory terms relating to probability, uncertainty, and causality (or effectiveness).

It should be repeated that all of these legal specifications contribute to the regulatory authority which an agency can exercise.

TYPE OF HARM

The harm component of a statute's risk definition generally consists of:

(1) descriptions of undesired outcomes, and/or

(2) descriptions of the "population at risk" or the objects of protection including the environment, etc.

Thus, "harm" from toxics consists of one or the other or both of the above components. Something happens to someone or something--that's harm. The first component of harm uses such terms as "danger," "injury," "cancer," "death" "adverse effect" but also includes mere "presence" (or discharge). Populations at risk include the "public," "wildlife," and the "environment". Some statutes, like SDWA §§1401, 1412 have both outcome and population at risk terms; other statutes have one or the other.

---

[14] However, the phrase referring to "available information" in Section 307(a) acts to temper the certainty requirements somewhat.

The definition of harm is generally the clearest aspect of a statute's definition of risk. Harm represents the outcome which the statute is designed to prevent. See Exhibit 9. As shown, harm statements range from "adverse effects on public health and welfare," to recitations of health effects (e.g., "serious irreversible disease"), to less specified harms such as "pollution" (Clean Water Act). No entries are included in Exhibit 9 for statutes which contain no specification of harm.

One important distinction needs to be made when analyzing the issue of "harm". The severity of health impacts has both an individual and a collective side. Although some legislation, such as the OSH Act, is written to afford protection to every single working individual, most laws are concerned about aggregate effects on public health. Thus, harm should be understood, in this context, as harm to populations. Of course, populations are composed of individuals who may have varying sensitivities to toxic exposures; nevertheless, unless there is a specially sensitive and/or large subgroup that can be identified, regulatory standards must be crafted to protect the general public from harm. Such standards may not necessarily ensure the protection of every individual in the exposed population.

Whether a substance regulated under one statute can be regulated under another, will depend in part on the required showing of harm. Exhibit 10 focuses on human health impacts, illustratively ranking them top to bottom from most serious and specific down to the most general and diffuse effects. Thus, a substance meeting a specific health effects criterion, all other things being equal, will probably satisfy all the criteria listed lower in Exhibit 10. The lower ones are more "inclusive". However, this ranking would hardly be dispositive in a litigation context.

Note that such terms as "adversely affect," "significant adverse impact," and "any adverse effect" may be functionally equivalent. Note also that it is difficult to assign a rank to the "unreasonable risk" formulation of the HMTA. In fact, TSCA is similarly ambivalent: is it supposed to protect against "injury to public health" or "unreasonable risks of injury to public health"? (Definitions of the risk that use a separate "risk of" term modifying the outcome are considered separately in the "Type of Risk" discussion.)

TYPE OF RISK

As shown by Exhibit 11, a number of statutes incorporate the concepts of risk, danger, or hazard in their definition of regulatory authority. Thus, these terms need some analysis. Again, no entries are included in the Exhibit and this discussion where statutes do not incorporate risk language.

At the start, it is helpful to point out that the term "risk" refers both (1) to the probability of some outcome (harm) occurring, and (2) to the probability of harm as well as its magnitude or severity. In general, the

EXHIBIT 9

STATUTORY DESCRIPTION OF THE HARM

Statute	Description of Harm and/or Objects of Protection
TSCA §4(a):	"Injury to health or the environment" OR "Significant or Substantial Human Exposure"
TSCA §4(f):	"Serious, widespread harm" to "human beings" from "cancer, gene mutations, or birth defects"
TSCA §§5(b)(4)(A), 5(f), 6(a)	"Injury to health or the environment"
CWA §311(b)(2)(A)	"[imminent and substantial danger to] the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches."
CWA §311(b)(4)	"[harmful to] the public health or welfare . . . including, but not limited to, fish, shellfish, wildlife, and public and private property, shorelines, and beaches."
CWA 307(a)	"Death, disease, behavioral abnormalities, cancer, mutations, physiological malfunctions, including malfunctions in reproduction, or physical deformations in any organisms or their offspring."
SDWA §1401(1), §1412(b)(1)(B)	"any adverse effect on the health of persons"
SDWA §1421	"the presence of any contaminant" "affect adversely the health of persons"
MPRSA §102(a)	"unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities"
RCRA §1004(5)	"an increase in mortality" or "in serious irreversible. or incapacitating reversible, illness." OR "[substantial hazard] to human health or the environment"

EXHIBIT 9 (Continued)

STATUTORY DESCRIPTION OF THE HARM

Statute	Description of Harm and/or Objects of Protection
RCRA §§3002,3,4	"[protect] human health and the environment"
FIFRA §§3(c), 3(d), 6(b)	"unreasonable adverse effects on the environment" or "any unreasonable adverse effect on the environment"
FIFRA §§25(c)	"Serious injury or illness to children and adults resulting from accidental ingestion or contact."
CAA §§108, 111, 157, 202, 211, 231	"endanger public health or welfare"
CAA §109	"[protect] the public health"
CAA §112	"increase in mortality or serious irreversible, or incapacitating reversible, illness."
CAA §157	"adverse effects on the stratosphere, especially ozone"
CERCLA §102	"[substantial danger to] the public health or welfare or the environment"
CERCLA §104	"death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunction (including malfunctions in reproduction) in . . . organisms or their offspring"
OSHA §6(b)(5)	"no . . . material impairment of health or functional capacity"
HMTA §104	"[unreasonable risk to] health and safety or property"
FDCA §§406, 408	"[protect] the public health"
FDCA §§402, 601	"injurious to health"
FDCA §§409(c), 512, 706(b)	"cancer in man or animal"

EXHIBIT 9 (Continued)

STATUTORY DESCRIPTION OF THE HARM

Statute	Description of Harm and/or Objects of Protection
PWSA 33 USC §1223	"vessel or cargo loss, or damage to life, property, the marine environment . . . to structures in, on, or immediately adjacent to the navigable waters or the resources within such waters"
PWSA 33 USC §1225	"damage to, or the destruction of, any bridge . . . [harm to] the navigable waters and the resources therein"
BFCLA 33 USC §391a	"hazards to life and property, for navigation and vessel safety, and for enhanced protection of the marine environment."
CPSA §§7, 8	"[unreasonable risk of] injury" defined as "death, personal injury, or serious or frequent illness."
FHSA §§2(f), 3(a)	"substantial personal injury or serious illness"
FHSA §§3(b), 2(q)	"[protect] the public health and safety"
PPPA §3	"serious personal injury or serious illness" affecting "children"
FFA §4	"fire leading to death or personal injury, or significant property damage"
NRC 42 USC §2201(b)	"protect health" or "minimize danger to life or property"
NRC 42 USC §§2077(d), 2111	"unreasonable risk to the health and safety of the public"

EXHIBIT 10

SAMPLE RANKING OF HEALTH EFFECTS CRITERIA

- serious widespread harm from cancer, gene mutations, or birth defects
  [TSCA §4(f)]
- death, disease, behavioral abnormalities, cancer, mutations, physiological malfunctions, physical deformations, birth defects
  [CERCLA §104, CWA §307(a)]
- [increase in] mortality, serious irreversible, or incapacitating reversible, illness
  [RCRA 1004(5), CAA §112]
- serious injury or [serious] illness
  [FIFRA §25(c), PPPA §1471]
- adversely affect the health
  [SDWA §1421]
- significant adverse impact on life
  [NRC]
- any adverse effect
  [SDWA §§1401, 1412]
- no material impairment
  [OSHA §6(b)]
- imminent and substantial danger
  [CWA §311(b)(2)(A)]
- danger to or endanger public health
  [CAA §§108, 111, 157, 202, 211, 231, CERCLA §102]
- unreasonable adverse effects or any unreasonable adverse effect
  [FIFRA]
- [unreasonable risk of] injury to health
  [TSCA §4(a), §5, §6]
- [unreasonable risk] to health
  [HMTA]

EXHIBIT 11

SPECIAL TYPES OF RISK INCORPORATED IN STATUTORY DEFINITIONS

Type of Risk	Statute
"significant risk"	TSCA §4(f)
"substantial danger"	CERCLA §102
"endanger"	CAA §§108(a), 111(b), 157(b), 202(a), 211, 231
"danger"	AEA 42 USC §2201(b)
"imminent and substantial danger"	CWA §311(b)(2)(A)
"substantial present or potential hazard	RCRA §1004(5)
"unreasonable and substantial risk"	FDCA (med. dev.)
"unreasonably degrade or endanger"	MPRSA §102(a)
"unreasonable risk"	TSCA §4(a), §5(b)(4)(A), §5(f), §6(a)
"unreasonable risk"	CPSA 15 USC §§2056, 2057
"unreasonable risk"	HMTA §104
"unreasonable risk"	FIFRA §§3, 6
"unreasonable risk"	AEA 42 USC §§2077(d), 2111

first meaning applies when the statutory language reads "risk of _____" followed by a definition of a harm, or when the term "risk" is preceded by such words as "significant" or "substantial". However, when "risk" is modified by the word "unreasonable," it usually refers both to probability as well as severity of harm, as do the terms "danger" or "endanger."

Many of the risk terms appearing in statutes have modifiers such as "significant," "substantial," or "unreasonable". With the exception of the term "unreasonable," the other modifiers all refer exclusively to the *magnitude* or probability of the risk.[15] This is how the Supreme Court used the phrase "significant risk" in its benzene decision.[16] There is no standard legal definition for ranking the terms significant and substantial; therefore, both terms should be considered equivalent.

The following sections discuss the concepts of (1) probability of harm embodied in the terms "significant" or "substantial" risk, (2) "endanger" or "danger," and (3) "unreasonable risk".

Probability of Harm. As the probability of harm presented by a toxic chemical exposure approaches zero, the risk may be deemed "insignificant" for purpose of designation and regulation. Conversely, as the probability increases, more strict regulatory standards may become appropriate. Thus, an essential component of a statute's definition of regulatable risk is the probabilty of harm criterion.

Most statutes do not directly address this aspect of risk but subsume it under such rubrics as "endanger the public health" or "presents an unreasonable risk". These approaches do require consideration of the probability of harm *together* with other risk factors (i.e., severity of harm, in the case of the "endanger" standard) and in view of compliance costs (in the case of "unreasonable" risk). These situations are discussed later. Certain statutory provisions do, however, incorporate terms usually interpreted as referring *solely* to the probability of harm. Thus, such phrases as "significant risk" or "substantial risk" imply that low probability risks are not subject to regulation. This is how the Supreme Court used the term "significant risk" in its benzene decision. However, it should be clear that even these phrases are somewhat ambiguous semantically since a low probability of a catastrophic event may still constitute a significant or substantial risk.

---

[15] "Imminent" risks refer to the velocity of the threat as opposed to its magnitude.

[16] *IUD v. API*, 448 U.S. 607 (1980) (plurality opinion). See also Linet and Bailey, "Benzene, Leukemia, and the Supreme Court," 2 *Journal of Public Health Policy* 116 (June 1981).

In its recent benzene decision, the Supreme Court noted some possible parameters to the term significant risk. The Court explained that if the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk "clearly could not be considered significant." On the other hand, "if the odds are one in a thousand that regular inhalation of gasoline vapors containing 2% benzene will be fatal, the risk could reasonably be considered significant." The Court, however, leaves a wide gray zone between .001 and .000000001. Most toxic substances risks will probably fall right in this gray zone.

- For example, under the Clean Water Act, the EPA determines the quantities of hazardous polluting substances which may be harmful to the public health and environment if spilled into the waters. The EPA accomplishes this using a worst case scenario combined with a significance factor of one-in-a-million risk of fatal cancer.[17]

Although the terms significant and substantial refer to the magnitude of the risk, the terms have not been defined quantitatively, either in the relevant statutes or in the case law. There has been very little judicial interpretation of these terms and, in any event, agency determinations of significant or substantial risk are likely to be accorded judicial deference.

The Meaning of "Endanger". Most apposite is the definition used by Judge Wright of the D.C. Circuit Court of Appeals reviewing the former "will endanger" standard of the Clean Air Act:

> Danger is not set by a fixed probability of harm, but rather is composed of reciprocal elements of risk and harm, or probability and severity. That is to say, the public health may properly be found endangered both by a lesser risk of a greater harm and by a greater risk of a lesser harm. Danger depends upon the relation between the risk and harm presented by each case and cannot legitimately be pegged to "probable" harm, regardless of whether that harm be great or small.[18]

---

[17] The Supreme Court's opinions may encourage some legal challenge to this methodology.. Conversely, agency regulations may be challenged as inadequate if they do not reduce the significant risk to at least a one in a billion chance of fatality.

[18] Ethyl Corp. v. EPA. 541 F. 2d 1, 31-3 (D.C. Cir. 1976) (en banc) (citations omitted) see also 38 FR 33734.

Judge Wright held that the EPA had been correct in interpreting "will endanger" to mean "presents a significant risk of harm."[19] As the Judge put it:

> . . . endanger means something less than actual harm. When one is endangered, harm is threatened; no actual injury need ever occur.[20]

The concept of "danger" was contrasted, in Ethyl, with the concept of "adverse effects"; the former was considered precautionary while the latter requires a showing of actual harm.[21]

The 8th Circuit Court of Appeals similarly interpreted the term "endangering" as it appeared in the Clean Water Act of 1970 (§112):

> [We] believe that Congress used the term "endangering" in a precautionary or preventive sense and, therefore, evidence of potential harm as well as actual harm comes within the purview of that term.[22]

How probable must the occurrence of a threatened harm be for it to constitute a danger or hazard? And how severe? As noted by the Ethyl Court, a "sophisticated case-by-case analysis is appropriate".[23] That is because danger is composed of reciprocal elements of risk (i.e., probability) and harm. The magnitude of the risk sufficient to justify regulation is inversely proportional to the harm to be avoided.

This suggests that there are minimal risk and harm levels that must be met for a "danger" to be present. For example,

- even the absolute certainty of de minimus (i.e., minor) harm might not jusify government action.[24]

---

[19] Ibid. at p. 12.

[20] Ibid.

[21] Ibid., at 15.

[22] Reserve Mining Co. v. EPA, 514 F.2d 492, 528 (8th Cir. 1975) (en banc).

[23] Ethyl, op. cit., at 18.

[24] Ethyl at p. 18.

- the possibility of a disaster of "ultimate severity and horrible consequences" may be so low as to allow minimal consideration and response.[25]

With respect to harm, cancer and lead poisoning would clearly not be considered de minimus. With respect to probability of occurrence, the legal requirement seems to be a "significant risk".[26] Because of the reciprocal relationship between risk and harm, the exercise of judgement is unavoidable and implicit in determinations of danger.[27]

> Danger is a risk, and so must be decided by assessment of risks as well as by proof of facts. . . .[28]

This requires weighing the relative risks of underprotection versus overprotection. An analogous balancing act is required whenever the term "unreasonable risk" appears in a statute; these situations are discussed next.

"Unreasonable" Risks and Effects

The term of art "unreasonable" appears in several statutes, either preceeding the word "risk" or modifying "adverse effects". The former usage appears in many sections of TSCA; the latter usage is prominent in FIFRA. The two phrases are equated by FIFRA which statutorily defines the latter in terms of the former. The MPRSA also uses the term "unreasonably" and other non-EPA statutes such as the Consumer Product Safety Act, and the Flammable Fabrics Act, employ unreasonable risk as a statutory criterion.

The term is derived from the law of products liability where recovery for injuries is predicated on a finding that the product in question is "unreasonably dangerous" to the consumer during ordinary or proper use. The courts have elaborated this legal doctrine quite extensively but the essence is that the utility of the product must be weighed against the magnitude of the danger.

In interpreting the Consumer Product Safety Act, the Court of Appeals for the Fifth Circuit held that the reasonableness of the risk is a function of the burden the standard would impose.[29] The burden includes both technical aspects (decreased utility, use of substitutes) as well as economic impacts.

---

[25] See Carolina Environmental Study Group v. U.S., 510 F.2d 796, 799 (D.C. Cir. 1975).

[26] See Ethyl at p. 20; Industrial Union Dept. v. American Petroleum Institute 448 U.S. 607 (1980) (benzene).

[27] Ethyl, at p. 20; Amoco Oil Co. v. EPA, 501 F.2d at 740-1 (D.C. Cir. 1974); AFL-CIO v. Hodgson, 499 F.2d 467, 475 (D.C. Cir. 1974) (asbestos).

[28] Ethyl, at p. 24.

Neither TSCA, FIFRA, nor the CPSA define the term "unreasonable risk". This was the congressional intent, as documented in the legislative histories of these laws. However, Congress was not otherwise totally silent:

> [T]he determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms and is not a factual determination but rather requires the exercise of judgement on the part of the person making it. . . . [Legislative History of TSCA, pp. 421-22.]

More specifically, the legislative history of TSCA indicated what factors should generally be weighed in making the determination that an unreasonable risk exists or may exist. Such a determination involves

> balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulations and other adverse effects which such proposed action may have on society. [Legislative History, p. 422.]

Similarly, Congress expressly omitted any definition of "unreasonable risk" from the Consumer Product Safety Act, stating

> Protection against unreasonable risks is central to many Federal and State safety statutes and the courts have had broad experience in interpreting the term's meaning and application. It is generally expected that the determination of unreasonable hazard will involve the Commission in balancing the probability that the risk will result in harm and the gravity of such harm against the effect on the product's utility, cost and availability to the consumer. An unreasonable hazard is clearly one which can be prevented or reduced without affecting the product's utility, cost or availability: or one which the effect on the product's utility, cost or availability is outweighed by the need to protect the public from the hazard associated with the product.[30]

---

[29] Aqua Slide 'N' Dive v. CPSC, 569 F.2d 831 (5th Cir. 1978).

[30] H.R. Rep. No. 1153, 92nd Cong., 2d Sess. 33 (1972).

This suggests a central role for cost-benefit analysis which is belied by the CPSA's legislative history:

> There should be no implication, however, that in arriving at its determination the Commission would be required to conduct and complete a cost-benefit analysis prior to promulgating standards under this act.[31]

The legislative history of TSCA indicates a similar Congressional point of view.

Although FIFRA does not define the term "unreasonable risk" it indicates that economic, social, and environmental costs and benefits of the use of pesticides are to be taken into account. This requires a cost-benefit type of an analysis.

THE REQUIRED NEXUS OR CONNECTION: CERTAINTY, CAUSALITY, EFFECTIVENESS

In order to justify the regulation of a chemical substance (or activity involving that substance), there must be a regulatory rationale. That rationale is typically based on some connection between (1) the chemical substance and a harm to be prevented or (2) the regulatory standard and protection. Without such a connection, a regulation would probably be deemed invalid.[32]

Even if a documented public health problem exists (i.e., if the type of harm criterion is satisfied), no regulation in response to this problem would be justified unless it can be shown:

- That an identifiable chemical substance or mixture is probably associated with the adverse effects, and
- The proposed standard would result in a decrease of negative effects.

The first point is essential to substantiate a designation decision. The second point is essential for regulation.

---

[31] Legislative History, see note 30, Ibid.

[32] The Supreme Court's benzene decision suggests that risk reduction must result from the imposition of a regulatory standard; without demonstrable resultant benefits, a health regulation has no rationale.

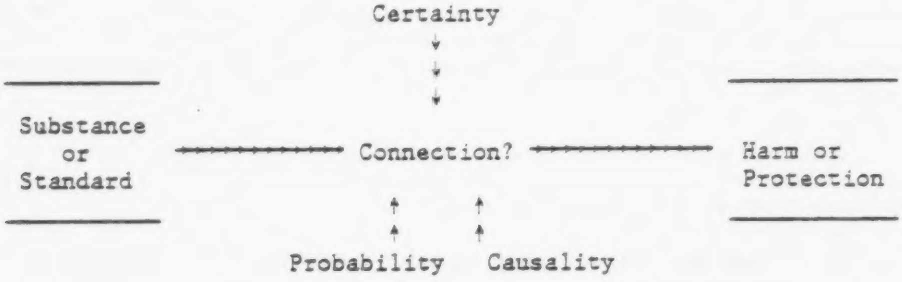
There are three dimensions to the connection requirement:

(1) Statutory language relating to the resolution of uncertainty regarding the causal role of the suspect chemical and the danger it poses (e.g., "may" harm vs. "will" harm);

(2) Statutory language relating to the causal role and probability of harm associated with a chemical exposure (e.g., "present", "cause", "contribute"); and

(3) Effectiveness language circumscribing agency discretion in fashioning standards (e.g., "necessary or appropriate" standards).

Three classes of statutory language are most pertinent to satisfying any rational nexus or connection requirement. Rules which do not adequately address these issues are subject to judicial invalidation as not meeting statutory criteria or as irrational and arbitrary exercises of administrative power.



The statutes reviewed employ different phrases to connect the pollutants with the harm or risk of harm to be avoided. For example, the Toxic Substances Control Act employs a variety of different phrases connecting substances and activities to "unreasonable risks":

"may present"	Section 4(a), 5(e)
"presents or may present"	Section 5(b)
"presents"	Section 7(a), 8(e)
"presents or will present"	Section 4(f), 5(f), 6(a)

"[exposure] occurs or may reasonably be anticipated [to occur]"	Section 5(e)
"likely to result"	Section 6(d)(2)
"would not result"	Section 6(e)

These terms relate to the resolution of uncertainty, probability of harm, and the causal role required for agency action. Other phrases (e.g., "necessary to protect the public health") relate to the connection required between the standard and the harm. See Exhibit 12. These topics and statutory language are discussed in detail next, except for probability of harm which has already been considered.

Resolution of Uncertainty

The legislative histories of most of the statutes reviewed recognize that the regulation of health and safety risks cannot usually be based on straightforward, definitive factual analyses. Rather, agencies will need to resolve uncertainties about the risks posed by particular substances. The statutes provide some guidance about this issue in a number of ways:

- The definition of the risk often incorporates a certainty requirement (e.g., *"may* present" an unreasonable risk versus *"will* present" an unreasonable risk).

- The factors for making a designation or regulation decision may address uncertainty through such a phrase as "best *available* evidence". Available evidence is usually not unambiguous.

- Burden of proof or evidentiary requirements (e.g., substantial evidence) determine *who* is responsible for resolving *how much* uncertainty.

- Finally, authority to designate or regulate chemicals *categorically* (as opposed to substance-by-substance) or to provide a margin of safety may implicitly affect burden of proof and allow for relatively more uncertainty to be tolerated.

Clearly, the *resolution of uncertainty* is an issue that permeates any analysis of statutory authority to designate and regulate chemical substances. Uncertainty can attach to all aspects of the definition of risk, including the probability and severity of the outcome, the population at risk, and the causal connection. Each of these four elements of risk is subject to

EXHIBIT 12

TYPES OF CAUSAL CONNECTIONS REQUIRED BETWEEN (1) CHEMICAL SUBSTANCES OR STANDARDS AND (2) RISK OF HARM

Causal Connection	Statute
Group 1--Present Conditionals Using "May"	
"may reasonably be anticipated to affect"	CAA §157
"may reasonably be anticipated to endanger"	CAA §§108, 111, 157, 202(a), 211, 231
"may reasonably be anticipated to result"	CAA §112
"may be harmful to"	CWA §311(b)(4)
"may present [danger or risk]"	TSCA §4(a), CERCLA §102
"may render [food injurious]"	FDCA §§402(a), 601
"may make [product injurious]"	USDA (PPIA, FMIA, and EPIA)
"may generally cause"	FIFRA §§3(d)(1)
"may cause"	FHSA §2(f), 3(a)
"may result in"	SDWA §§1421
"may have [any adverse effect]"	SDWA §§1401, 1412
"may affect [adversely]"	SDWA §1421
Group 2--Present Tense Unconditional	
"causes or contributes to"	CAA §§108, 111, 112, 202, 211, 231
"presents [danger or risk]"	CWA §311(b)(2)(A), CPSA §8
"generally causes"	FIFRA §6(b)
"[is] associated with"	CPSA §8
"presents or will present"	TSCA §§4(f), 5(b)(4)(A), 5(f), 6(a)
"ordinarily render[s]"	FDCA §402(a), USDA (PPIA, FMIA, and EPIA)

EXHIBIT 12 (Continued)

TYPES OF CAUSAL CONNECTIONS REQUIRED BETWEEN (1) CHEMICAL SUBSTANCES OR STANDARDS AND (2) RISK OF HARM

Causal Connection	Statute
Group 3--Future Tense Unconditional	
"will or may reasonably be anticipated to cause"	CERCLA §104
"will not generally cause"	FIFRA §§3(c)(5), 3(d)
"will not [unreasonably degrade or endanger]"	FIFRA §3(c)(5)
"will cause"	CWA §307(a)
"will not cause"	FIFRA §3(c)(7)(C)
"would not cause"	FIFRA §3(d)(3)
"would not significantly increase [the risk of]"	FIFRA §3(c)(7)(A),(B)
"would not constitute:	AEA 42 USC §2077(d)
Group 4--Causal Connection Between Standard and Harm	
"in order to protect against"	FIFRA §25(c)
"is necessary to prevent"	FIFRA §3(d)(2)
"is necessary to protect"	PWSA §1225
"is required to protect"	PPPA §3
"if required to assure"	FDCA §409
"necessary to protect"	FDCA §§406, 408; FHSA §3(b)
"necessary or appropriate"	HMTA §105, OSHA §3(8)
"may be necessary"	USCG (BFCLA and DCA)
"is reasonably necessary"	CPSA §7
"may be" or "is" "needed to protect"	FFA §4
"necessary or desirable"	AEA 42 USC §2201(b)

generally imprecise estimation based on extrapolations from scientific studies or other data. Each estimate, moreover, should be thought of as "most likely" with confidence limits describing the probable range of the estimate.

Population at risk, probability and severity of harm are three variables which effectively set the bounds on what is a public health problem for which regulation might be necessary or appropriate.

In many instances, the limited available data can support alternative and incompatible "scientific" interpretations. For these situations, these elements cannot be determined based on "facts" but become "judgment" calls. These "policy judgments," as they are also called, are usually within agency discretion so long as they are not "arbitrary or capricious" (i.e., without rational foundation). In those situations, much regulatory discretion will exist to resolve uncertainty.

For example, an agency might estimate that of every 1,000 people exposed to a substance, three might be "reasonably expected to" contract fatal cancer. However, the 95 percent confidence interval[33/] on this incidence estimate might range from one to 100, or from one to 10 if there were less uncertainty. The same reasoning applies to estimates of the population at risk. Both of these risk variables are measured using cardinal scales which are quite amenable to numerical calculations of uncertainty.

Uncertainty regarding the severity of harm must be treated differently. In some instances, the severity of the harm is quite certain, in others less so. Quite often, the possible harms do not form a continuum and are thus not well-suited to conventional numerical confidence limits. For example, among the health effects of benzene exposure are leukemia, aplastic anemia (often fatal), various cytopenias, and subclinical chromosomal aberrations. Statutes using relatively broad harm concepts (e.g., endanger public health) would seem to permit more uncertainty regarding severity of effects than statutes defining more precise types of outcomes (see Exhibit 11).

Finally, uncertainty regarding causality needs to be distinguished from uncertainty regarding probability. For example, in the case of coke oven emissions, the probability and severity of health effects are both relatively certain; what is not known is the specific causal agent or chemical substance. Conversely, the issue of causality may become moot when both the probability and severity of health effects are highly uncertain but expected to be low. In other cases, CFCs for example, control standards may be grounded in a very confident causal role assessment (i.e., stratospheric effects), although the probability and severity of health impacts are less certain.

[33/] This is a standard statistical measure of uncertainty.

"May" Versus "Will"

Statutory language referring to uncertainty is ambiguous. For example, the term "may" as in "may cause" or "may endanger" has two possible interpretations. "May" might refer either to (1) the probability of public health impacts or to (2) some uncertainty regarding the risk. Conversely, the expression "will," as in "will endanger," can refer either to high probability or high levels of certainty. In either case, courts read statutory language very closely and have found as deficient certain agency rules issued under a "will cause" standard that would have probably been upheld under a "may cause" standard.[34]

There are several legal cases and other authorities which explicitly discuss the certainty/probability issue as embodied in the terms may or will:

- MCA v. Costle interpreted the term "will be harmful" which formerly appeared in Section 311 of the Clean Water Act but was changed to "may" as a result of this decision.[35]
- EDF v. Costle[36] interprets the term "may" in Section 1412 of the Safe Drinking Water Act
- Several cases interpret the "may render injurious" standard of the Food, Drug, and Cosmetic Act, Section 402.
- The legislative history of TSCA discusses the Congressional intent in using "may" in TSCA Section 4(a).
- The legislative history of CERCLA compares the use of "may" in CERCLA Section 102 to the unconditional language in the designation criteria of CWA Section 311(b)(2).

All of these authorities suggest that the term "may" allows for more agency discretion on designation and regulation than do other unconditional terms.

For example, EPA's designation of reportable quantities under the former wording of Section 311(b)(4) (i.e., quantities which "will be harmful" at

---

[34] See, MCA v. Costle, 455 F.Supp. 968 (W.D. La. 1978).

[35] See "Clean Water Act Regulatory Review" in ICF Incorporated, Chemical Substances Designation, Volume 2 (1981).

[36] EDF v. Costle, 578 F.2d 337 (D.C. Cir. 1978).

"such times, location, circumstances, and conditions" when discharged) was invalidated as arbitrary and capricious because no demonstration was made linking actual harm to reportable quantities. Section 311(b)(4) was amended, following the decision, to allow EPA to determine those quantities of hazardous substances "which may be harmful" and these rules have not been legally challenged.

The Safe Drinking Water Act (SDWA) requires regulation of contaminants which "may have an adverse effect on health." The D.C. Court of Appeals, in generally upholding the interim regulations issued by the EPA, cited the legislative history of the SDWA which authorizes EPA to regulate contaminants despite potential uncertainty about health effects:

> The words used by the Committee were carefully chosen. Because of the essentially preventive purpose of the legislation, the vast number of contaminants which may need to be regulated and the limited amount of knowledge presently available on the health effects of various contaminants in drinking water, the Committee did not intend to require conclusive proof that any contaminant *will* cause adverse health effects as a condition for regulation of a suspect contaminant. Rather, all that is required is that the administrator make a reasoned and plausible judgment that a contaminant may have such an effect.[37]

"May render injurious" is a criterion for determining whether a substance that is added to food makes that food "adulterated" under Section 402(a) of the Food, Drug, and Cosmetic Act. Several courts, including the U.S. Supreme Court have interpreted that phrase to mean that the Government need not prove *conclusively* that a food containing an added poison *must* cause injury.[38] Rather, if the food

> "cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer", the statutory criterion is not met.[39]

---

[37] EDF v. Costle, 578 F.2d 337, 11 ERC 1209 (D.C. Cir. 1978), citing H.R. Rep. No. 93-1185, 92d Cong., 2d Sess. (1974) at p. 10 (emphasis in original).

[38] *U.S. v. Lexington Mill and Elevator Co.*, 232 U.S. 399 (1914) (flour treated with nitrogen peroxide gas).

[39] *Ibid*., at 411.

Another court has pointed out that

> The word "may" connotes a reasonable possibility. It does not mean that a food may be prohibited absent absolute certainty that no one under the most extreme circumstances could be harmed. Nothing in the Act or legislative history suggests that Congress intended to proscribe a food simply because it was physically possible for one to consume enough of it to harm oneself. The Supreme Court has taken notice that a person could be harmed by ingesting a certain level of table salt, or even water.[40]

This formula has been applied by other courts which have cast the requirement as a finding whether the food poses "a reasonable possibility of injury to anyone's health."[41] This type of determination should consider the various ways the food might be used, as well as the special sensitivities of such groups as the sick, the young, or the aged.[42] Thus, the "may render injurious" language of the FDCA requires a showing of lesser probability or certainty of harm than a "will render" criterion and also allows an agency to consider effects on especially vulnerable segments of the population.[43]

The criterion necessary to trigger Agency action under Section 4(a)(1)(A) (i.e., test rules) of TSCA is "may present" an unreasonable risk. The legislative history states that this criterion is intended:

> "to focus the Administrator's attention on those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine the effects of the substance or mixture on health or the environment. The Administrator need not show that the substance or mixture does or will present a risk." [Legislative History, p. 674. (emphasis added)]

---

[40] U.S. v. Anderson Seafoods, Inc., 447 F.Supp. 1151, 1155 (N.D. Fla. 1978), citing Flemming v. Florida Citrus Exchange, 358 U.S. 153, 163 (1958).

[41] See, U.S. v. Anderson Seafoods Inc., 447 F.Supp. 1151, 1156 (N.D. Fla. 1978); Berger v. U.S., 200 F.2d 818, 821 (8th Cir. 1952) (dicta).

[42] See; Lexington Mill at p. 411. See also Wood v. U.S., 286 F.84 (7th Cir. 1923), where soda was not found to be adulterated because one would have to consume 150,000 bottles to achieve a "dose" of arsenic.

[43] See, Merrill and Schewel, "FDA Regulations of Environmental Contaminants in Food," 66 Va. L. Rev. 1357, 1372 (1980); but see, Environmental Standards and Sensitive Populations (Conservation Foundation, 1981).

The House Report also discusses the choice of the term "may".

> It should be noted that the bill does not require the Administrator to find that a substance or mixture does cause or significantly contribute to or will cause or significantly contribute to an unreasonable risk. Such a finding requirement would defeat the purpose of the section, for if the Administrator is able to make such a determination, regulatory action to protect against the risk, not additional testing, is called for. However, the term "may" as used in the phrase "may cause or significantly contribute to" does not permit the Administrator to make a finding respecting probability of a risk on the basis of mere conjecture or speculation, i.e., it may or may not cause a risk. [Legislative History pp. 424-5.]

Thus, use of the conditional term "may" permits a fairly broad exercise of agency discretion, although it does not allow arbitrary decisions.

Designation criteria for CERCLA Section 102 hazardous substances includes the phrase "may present substantial danger" which was characterized as requiring a "lower threshold for designation" than that included in the designation criteria of CWA Section 311(b)(2) hazardous substances (i.e., "present an imminent and substantial danger"). In reference to the earlier Senate version of CERCLA, S.1480, Congressional intent in defining Section 102 hazardous substances was "to afford ... broad discretion in designating substances."

In summary, any analysis of regulatory integration must take into account statutory requirements or authorizations relating to the issue of uncertainty. As discussed earlier, the definition of risk will, in particular cases, incorporate a position on uncertainty, but other statutory provisions (e.g., decision factors or criteria, burden of proof provisions) also need to be considered. In the next section, we further discuss the related topics of probability and/or certainty of causation or protection.

The Causal Connection

There are a number of issues involved in the notion of causality. Two of those issues are the focus of this discussion:

(1) Direct versus indirect causation, and

(2) Cumulative versus incremental causation as a basis for regulation.

In discussing the first issue, we will review the statutory terms used (e.g., "pose", "present", "render", "cause"). The second issue requires a review of legal decisions that have considered the problem.

Direct vs. Indirect Causation

Although some connection must be established between the presence of or exposure to pollutants and potentially resulting health effects, the statutes often use specific language that broadens the possible causal roles for which chemicals may be subject to control. The intent behind the use of these terms is to include both direct and indirect health effects.

There was much debate surrounding the proper connective to be used in TSCA. Ultimately, though, the conference committee adopted the Senate language may "present" in lieu of the House formula may "cause or significantly contribute to". In choosing this term, the conferees intended

> that [EPA] . . . be able to address substances and mixtures which indirectly present unreasonable risks, as well as those which directly present such risks. Further, the conferees do not intend that a substance or mixture must be the single factor which results in the presentation of the risk [Legislative History of TSCA, p. 673.].

Despite this, the terms used in the different laws are not consistent. The most widely-used terms are:

"cause or contribute to"	RCRA 1004(5)(A); CAA §108, §111, §202, §211, §231
"render"	FDCA §402(a), §601
"present"	TSCA §§4, 5, & 6; CWA §311(b)(2)(A); CERCLA §102; CPSA §8
"cause"	CWA §307(a); FIFRA §3, §6; CERCLA §104, FHSA
"affect"	SDWA §1421, CAA §157
"result"	SDWA §1421, CAA §112
"pose"	RCRA §1004(5)(B), HMTA §104

Some phrases explicitly mention both direct and indirect effects (e.g., CERCLA §104). Other statutory provisions incorporate a two-stage causal requirement (e.g., TSCA §4(a), SDWA §1421, CAA §108, §111, §157, §202, §211, §231). See Exhibit 13. The Clean Air Act formulae were largely adopted in 1977 to clarify the bases of air pollution regulation. To regulate under several sections, EPA must show that (1) emissions cause or contribute to air pollution which (2) air pollution endangers the public health.

Cumulative vs. Incremental Effects

Exposures to hazardous chemicals often have multiple sources. For example, sources of lead include food, automotive emissions, industrial pollution of air and water, etc. When assessing the health risks of a substance such as lead, it is difficult--almost arbitrary in fact--to allocate portions of the health damage to the different sources of the pollutant. Despite this difficulty, statutory provisions usually authorize the regulation of only one class of sources. Typically, legal controversy surrounds the decision to regulate an exposure increment; affected industries often contend that the exposure increment being regulated is not, in itself, hazardous; agencies counter that cumulative impacts must be considered and different pollution sources may have varying degrees of susceptibility to control.

The 1977 Amendments to the Clean Air Act clarified this issue by using the phrase *"cause or contribute* to air pollution which may reasonably be anticipated to endanger" public health. This formulation allows consideration of aggregate air pollution impact, regardless of source (i.e., mobile vs. stationary). Congress authorized EPA to consider all sources of exposure to the pollutant--food, water, air, etc.--in determining health risk.

> However, the *Ethyl* Court agreed with EPA's position that the contribution must be "significant" before regulation is proper. Moreover, "while the incremental effect of lead emissions on the total body burden is of no practical value in determining whether health is endangered, it is of value, of course, in deciding whether the lead exposure problem can be fruitfully attacked through control of lead additives."[44]

However, the court did not agree that the increment of exposure *itself* must cause a significant health hazard. This view is consistent with the case of *People of California v. Department of Navy*[45] which held that "It is the cumulative effect of innumerable 'insignificant' pollutions which has hung an environmental cloud over our planet".[46]

An analogous controversy has arisen over the regulation of environmental contaminants and additives in food. The Fifth Circuit Court of Appeals rejected the contention that the added increment alone must render food injurious for regulation to be necessitated; rather, regulation is called for whenever the total amount of the pollutant may be injurious so long as some portion of the contamination is attributable to acts of man.[47] The Court pointed out that the increment of the contaminant must create or increase "a potentiality of injury to health" and it need not, by itself, be shown to render food potentially injurious.

---

[44] *Ethyl* at p. 31, n. 62. See Wilkey, dissent, *Ibid*., p. 94.

[45] 431 F. Supp. 1271 (N. D. Cal. 1977).

[46] *Ibid*., at p. 1294.

Likewise, the use of the term "present" in TSCA reflects the intent to grant authority over this type of toxic exposure:

> Oftentimes an unreasonable risk will be presented because of the interrelationship or cumulative impact of a number of different substances or mixtures. The conferees intend that the Administrator have authority to protect health and the environment in such situations. [Legislative History, pp. 673-4.]

Several of the provisions of the Food, Drug, and Cosmetic Act specifically require the FDA, when setting tolerances, to consider the other ways that consumers may be affected by the same or related hazardous chemicals. However, apart from past IRLG activities, there have been only limited attempts, in general, to integrate standard-setting across agencies or among exposure sources to take multiple exposures into account. This remains for the most part an unexplored frontier for policy-related research.

STATUTORY BASES AND FACTORS FOR LEVEL OF PROTECTION DECISIONS

The statutes reviewed often differ as to the amount of protection or risk reduction they authorize. Many statutes refer only to the issuance of standards "necessary," "adequate" or "sufficient" to protect the public health. Some give more detailed guidance (e.g., ample margin of safety, no material impairment of health). Others address this issue by prescribing particular factors as the basis for standard-setting (or as matters for consideration). Of this last group, many laws allow for the balancing of risk and cost considerations, which is another way of establishing a level of protection. See Exhibit 13. These issues are discussed in this part of the analysis.

Statutory language often guides the designation and standard-setting process by explicitly providing a specified basis for making decisions as well as factors to be considered. In discussing these issues, it is essential to distinguish among:

- bases for decisions,
- factors which must be considered,

---

[47] U.S. v. Anderson Seafoods, Inc., 622 F. 20 157, 161-2 (5th Cir. 1980).

EXHIBIT 13

REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION

Statutory Provision	Risk Factors	Economic Factors	Technical Factors	Cost-Benefit Analysis
TSCA §4(a)	"Unreasonable risk" is basis for issuance of test rule in §4. However, §2(c) suggests that economic impacts should be considered. (§4(a)(1)(A))		Data must be "insufficient". Testing must be "necessary" to remedy existing inadequate data base.	Not addressed in statute. No formal benefit-cost analysis required (legislative history).
	Risk rationale (production of exposure) is alternate basis for issuance of test rule. (§4(a)(1)(B))	Not addressed in §4. However, §2(c) suggests that economic impacts should be considered.	Data must be "insufficient". Testing must be "necessary" to remedy existing existing inadequate data base.	Not addressed in statute. No formal benefit-cost analysis required (legislative history).
TSCA §4(b)	Test standards must require the testing of effects which may present an unreasonable risk, including "carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects" "persistence, acute toxicity, subacute toxicity, chronic toxicity" and other effects or characteristics which may present such a risk. (§4(b)(2))	In determining standards for the development of test data, EPA's considerations must include the relative costs of the various test protocols and methodologies" and the "reasonably foreseeable availability" of needed facilities and personnel. (§4(b)(1))		Not addressed in statute.
TSCA §5(b)(4)(A)(ii)	"All relevant factors" must be considered in finding that a chemical substance presents or may present an unreasonable risk, including health and environmental effects and exposure	Not addressed in statute. Determination of unreasonable risk requires consideration of the benefits of the substance and the availability of substitutes, according to the Legislative History. Section 2(c) suggests that economic impacts must be considered.		Not addressed in statute. Determining unreasonable risk requires a balancing of the probability and severity of harm against the benefits of the substance involved, taking into account the availability of substitutes, according to the Legislative History.
TSCA §6	Unreasonable risk rationale is statutory basis for regulation. (§6(a)) Health and environmental effects of the substance or mixture and magnitude of exposure must be considered in promulgating a §6(a) rule. (§6(c)(1)(A) and (B))	Requirements shall be imposed "to the extent necessary to protect adequately against such risk using the least burdensome requirements. ..." (§6(a)) EPA must also consider [(C)] the benefits of the substance and the availability of substitutes and [(D)] "the reasonably ascertainable economic consequences ... after consideration of the effect on the national economy, small business, technological innovation. ..." (§6(c)(1)(C) and (D))		See comment above. If the risk could be eliminated or reduced to a sufficient extent by actions taken under other EPA authorities, the EPA must compare the estimated costs of compliance and the relative efficiency of the alternatives. (§6(c)(1))

Note: Section 2(c) of TSCA expresses Congress' intent that the environmental, economic, and social impact of any action shall be considered.

EXHIBIT 13

REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Risk Factors	Economic Factors	Technical Factors	Cost-Benefit Analysis
CWA §307	In listing toxic pollutants, EPA must take into account "the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms ... [and their] importance ..., and ; the nature and extent of the effect of the toxic pollutant ..." (§307(a))	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.
	In establishing effluent standards, EPA must take into account the risk factors listed above as well as "the extent to which effective control is being or may be achieved under other regulatory authority." (§307(a)(2))	Effluent limitations must reflect the "application of the best available technology economically achievable." (§307(a)(2))		Effluent standards shall be at the level which "provides an ample margin of safety." (§307(a)(4))
	Effluent standards must provide "an ample margin of safety." (§307(a)(4))		If compliance within one year is "technologically infeasible" the compliance date shall be established for the earliest date by which compliance can be feasibly attained, but no later than three years after promulgation of standard. (§307(a)(6))	
CWA §311	Risk rationale is statutory basis for designating hazardous substances and reportable quantities. (§311(b)(2), (4))	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.

EXHIBIT 13

REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION

(continued)

Statutory Provision	Risk Factors	Economic Factors	Technical Factors	Cost-Benefit Analysis
SDWA §1412	EPA must establish, based on an NAS study, the recommended maximum contaminant level (MCL) for each contaminant which may have an adverse effect on health. The MCL shall be set at a level at which "no known or anticipated adverse [health] effects "occur and which allows an "adequate margin of safety." (§1412(b)(1)(B))	Not addressed in statute.	Not addressed in statute.	
	Revised primary drinking water regulations shall be set as close to the MCL's as is "feasible" (§1412(b)(3))			Not addressed in statute. EPA must strike a balance between promotion of public welfare and avoidance of unnecessary expense, dicta in EDF v. Costle, 11 ERC 1209 (D.C. Cir. 1978).
		"Feasible" means "with the use of the best technology treatment techniques, and other means, which ... are generally available (taking costs into consideration)." (§1412(b)(3)).		
			Drinking water regulations must be amended "whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons." (§1412(b)(4)).	
SDWA §1421	Risk rationale is statutory basis for regulating underground injection which "endangers" drinking water.	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.
MPRSA §102	No "unreasonable" degradation or endangerment of "human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities" is statutory basis for issuing ocean dumping permits. (§102a)			Use of term "unreasonable" implies some sort of balancing of interests, although not necessarily a formal cost-benefit analysis.
	EPA must consider enumerated risk factors in establishing ocean dumping permit criteria. (§102(a))	EPA must consider the need for dumping and its economic effects in establishing permit criteria. (§102(a))		

EXHIBIT 13

REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Risk Factors	Economic Factors	Technical Factors	Cost-Benefit Analysis
RCRA §3001	Risk rationale is statutory basis for identifying hazardous waste characteristics and listing such wastes. (§3001(b))	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.
RCRA §3002-4	Risk rationale is statutory basis for standards	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.
FIFRA §3(c)(5), §3(c)(7), §3(d), §6(b)	Unreasonable adverse effects is the statutory basis for regulation which is defined to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits." (§2(b)(b))			Not addressed in statute. Implicit in balancing approach.
FIFRA §25(c)	Risk rationale is basis for packaging standards.	Not addressed in statute.	Packaging requirements must be consistent with those established by the Poison Prevention Packaging Act.	
CAA §108(a)	Risk to public health and welfare is statutory basis for listing decision. Listing is a discretionary decision, Thompson v. Chicago, 7 ERC 1682 (N.D. Ill. 1975)	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.
CAA §109	Primary ambient air quality standards must be based on air quality criteria, must allow an "adequate margin and safety," and must be "requisite to protect the public health" from adverse health effects. (§109(b)(1)) Primary standard must protect against uncertain as well as certain harms. LIA v. EPA, 14 ERC 1906 (D.C. Cir. 1980)	D.C. Circuit Court of Appeals held that the costs and technical feasibility of attaining the standards are not to be considered in establishing them, LIA v. EPA, 14 ERC 1906 (1980), referencing the legislative history. Sections 108-110 are "technology-forcing" provisions; the attainment of the primary, health-based standards takes precedence over the cost and present technological feasibility of achieving the requisite control, Ethyl Corp. v. EPA, 541 F. 2d 1, 14 (D.C. Cir. 1976), citing legislative history and other decisions.		Not required by statute, LIA v. EPA.

EXHIBIT 13

REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Risk Factors	Economic Factors	Technical Factors	Cost-Benefit Analysis
CAA §111	New source categories listed on basis of health risk. (§111(b))	Not mentioned for listing.	Not mentioned for listing.	Formal cost-benefit study not required. Portland Cement Ass'n. v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973).
	New Source Performance Standards (§111(a)) must also take into account "any non-air quality health and environmental impacts ..."	Economic and Technological feasibility must be considered for standards.	Economic and technological feasibility must be considered for standards	
		For standards, the cost must be taken into account when setting emission limits, as well as energy requirements. Portland Cement Ass'n v. Ruckelshaus, 513 F.2d 506 (D.C. Cir 1976) (§111(a))	New source performance standard must be based on the "best technology system of continuous emission reduction ... which has been adequately demonstrated." This is a technology-forcing provision.	
CAA §112	Risk to public health is statutory basis for listing. (§112(a))	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.
	Emission standard must be set at the level which provides an "ample margin of safety" to protect the public health. (§112(b))	Not addressed in statute. EPA has incorporated these factors administratively for carcinogen standards.	Not addressed in statute. EPA has incorporated these factors administratively for carcinogen standards.	Not addressed in statute. EPA has used a form of cost-benefit analysis in setting standards for carcinogens.
CAA §157	Risk rationale is statutory basis for regulation. (§157(b))	Regulations must take costs and feasibility of controls into account. (§157(b))		Not addressed in statute.
CAA §202(a)	Risk rationale is statutory basis for regulating motor vehicle emissions. (§202(a)(1))	Regulations must take effect after the time necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance. (§202(a)(2))		Not addressed in statute.
	Emission control devices shall not be used to comply with standards if the device will cause or contribute to an "unreasonable risk" to public health, welfare, or safety. (§202(a)(4))			

EXHIBIT 13

REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Risk Factors	Economic Factors	Technical Factors	Cost-Benefit Analysis
CAA §211(c)	Risk rationale is statutory basis for regulation of fuels and fuel additives. (§211(c)(1))	EPA must consider "other technologically or economically feasible means" of achieving §202 emission limits before regulating fuels or fuel additives. (§211(c)(2)(A))		"Available economic data" must be considered "including a cost benefit analysis" of controlling fuel additives versus emission controls. (§211(c)(2)(B))
	"All relevant medical and scientific evidence available" must be considered. (§211(c)(2)(A))	"Available economic data" must be considered. (§211(c)(2)(B))		
	To prohibit fuels of additives, EPA must find that the prohibition "will not cause the use of any other fuel or ... additive which will produce emissions which will endanger the public health or welfare to the same or greater degree. ..." (§211(c)(2)(C))			
CAA §231	Risk rationale is statutory basis for regulating aircraft emissions (§231(a)(2))	Regulations must take effect after the period of time "necessary (after consultation with the Secretary of Transportation" to permit the "development and application of the requisite technology, giving appropriate consideration to the cost of compliance." (§231(b))		
CERCLA §102	Risk rationale is statutory basis for designation of hazardous substances	Not addressed in statute.	Not addressed in statute.	Not addressed in statute.
OSHA §6(b)(5)	Risk rationale is statutory basis for regulation of toxic materials	Standards for toxic materials must protect health "to the extent feasible" which includes both economic and technological feasibility. (§6(b)(5) interpreted by IUD v. Hodgson, 499 F. 2d 467, 478 (D.C. Cir. 1974).		Cost-benefit balancing is not allowed or required for setting standards. (ATMI v. Donovan)
	Risk must be "significant" to justify any regulation, Industrial Union v. API, 100 S Ct. 2844 1980.		A standard must be "necessary or appropriate" to provide healthful places of employment. (§3(8))	§3(8) does not incorporate cost benefit analysis requirement. ATMI v. Donovan, 9 OSHC 1913 (1981).
DOT/HMTA	Unreasonable risk is statutory basis for regulation (§104)	Not addressed in statute.	Regulations must be "necessary or appropriate." (§105)	Not addressed in statute.

EXHIBIT 13

REQUIRED BASES AND CONSIDERATIONS FOR DESIGNATION/REGULATION
(continued)

Statutory Provision	Risk Factors	Economic Factors	Technical Factors	Cost-Benefit Analysis
DOT/USCG	Risk rationale is statutory basis for regulation (PHSA, DCA, BPCLA).	Not addressed in statutes.	Not addressed in statutes.	Not addressed in statutes.
FDCA	Risk rationale is statutory basid for regulation. (§406, §408, §402(a), §601)	Not addressed in statutes. Economic and technological factors must be considered for §408.	Not addressed in status.	Not addressed in statutes.
	Safety is statutory basis for regulation (§409, §505, §512, §706.)	Not addressed in statutes.	Not addressed in status.	Not addressed in statutes. For medical devices, new drugs and new animal drugs, therapeutic risks and benefits are weighed. For food additives (§409), color additives (§706), and new animal drugs (§512), no carcinogens may be approved.
CPSA	"Unreasonable risk" is statutory basis for regulation. A standard must be "reasonably necessary" to prevent or reduce the unreasonable risk (§7(a)), or no "feasible" standard "would adequately protect" against the risk in case of a regulatory ban (§8).			Unreasonable risk determination requires balancing risk, technical, and economic factors but not a cost-benefit analysis, Legislative History, Aqua Slide 'N' Dive v. CPSC, 569 F.2d 831 (5th. cir. 1978).
	The CPSC must consider the degree and nature of the risk the rule is to reduce or eliminate. (§9(c)(1)(A))	The CPSC must consider the public's need for the product and the probable effect of a rule on the utility, cost, or availability of products to meet the need. (§9(c)(1)(C)) The CPSC must consider any means of minimizing adverse effects on competition or disruption or dislocating of manufacturing and other commercial practices consistent with the public health and safety. (§9(c)(1)(D))		
FHSA	Risk rationale is statutory basis for regulation.	Not addressed in statute.	If no feasible cautionary labeling can adequately protect the public health, a ban may be imposed.	Not addressed in statute.
PPPA	Risk rationale is a statutory basis for requiring special packaging.	Not addressed in statute.	Technical feasibility is a statutory basis for regulation.	Not addressed in statute.

- factors which may be considered, and
- factors which may not be considered.

In ambiguous situations, the administrative process can take the lead in interpreting legislative language, subject to review in the Courts or Congress. In general, a substantial amount of agency discretion exists to read statutory language in permissive fashion. Thus, while statutory directives must be heeded, they can be interpreted creatively (e.g., EPA implementation of section 112 of the Clean Air Act). However, explicit direct statutory language is a major force in defining regulatory authority. Thus, it is an "established maxim that health-related legislation is liberally construed to achieve its purpose."[48] On the other hand, the same Court of Appeals has written that "when Congress directs an agency to consider only certain factors in reaching an administrative decision, the agency is not free to trespass beyond the bounds of its statutory authority by taking other factors into account."[49]

In the literature, health and environmental protection laws are often divided into two contrasting groups. The first group is sometimes termed "health only laws" or "zero risk" legislation although these are not the same; the second group is characterized by such labels as "balancing."[50]

Although illustrative, these categories oversimplify. For example, the Clean Air Act is often criticized as being too much of a "health only" or zero risk law, but economic considerations are an inescapable part of the regulatory program as a whole. It is true that National Ambient Air Quality Standards are based solely on health effects data and analysis; however, the design of emission control strategies to attain those standards may be based solely on economic impact concerns. Likewise, compliance with other Clean Air Act health-based standards is conditioned on economic and technical feasibility.

---

[48] Ethyl Corp. v. EPA, 541 F.2d 1, 31 (D.C. Cir. 1976).

[49] LIA v. EPA, 14 ERC 1906, 1920 (D.C. Cir. 1980).

[50] For example, the Office of Technology Assessment distinguishes "Risk-Based Laws" (also erroneously called "zero-risk laws"), "Balancing Laws," and "Technology-Based Laws." See Technologies for Determining Cancer Risk from the Environment (OTA, June 1981); William Rodgers uses the terms "cost-oblivious," "cost-effective," "cost-sensitive," and "cost-benefit" statutes in "Benefits, Costs and Risks: Oversight of Health and Environmental Decision-Making," 4 Harv. Env. L. Rev. 191 (1980); James Leape classifies laws into "Balancing Statutes" and "Health-Only Statutes," in Quantitative Risk Assessment," 4 Harv. Env. L. Rev. 86 (1980). The classification of laws by these different commentators and others has not been consistent.

Thus, while certain statutory provisions may be "health-biased," it is essential to analyze the entire regulatory program to assess the "balanced" or "biased" nature of the law.

In addition, most "health-only" provisions are associated with pure designation decisions. For example:

- TSCA section 5(b)(4)(A) is purely a designation provision which does not itself authorize regulation, as is CWA section 311, RCRA section 3001 and CERCLA section 102.

In many other instances, statutes combine a risk-based designation provision with cost-sensitive regulatory authority. TSCA section 4(a) designation of substances for issuing test rules is based solely on risk criteria but section 4(b) testing standards are to be based on cost and feasibility considerations. See Exhibit 14. Only a limited number of statutory provisions appear to authorize regulation without consideration of economic factors. These are:

- Safe Drinking Water Act section 1421 (Underground Injection Control)
- RCRA sections 3002-4 (Standards for Generators, Transporters, Treaters, and Disposers of Hazardous Wastes)
- FIFRA section 25(c) (Special Packaging Standards for Pesticides)
- CAA section 112 (National Emission Standards for Hazardous Air Pollutants)

In the case of the NESHAPs program, the EPA has incorporated economic analysis into its standard-setting for airborne carcinogens. The role of economic factors in standard-setting under RCRA may be resolved through litigation. Many non-EPA laws similarly avoid mention of the role of economic factors. This applies to many of the DOT, FDA and USDA laws but not to the OSHA Act, the Atomic Energy Act, or the Consumer Product Safety Act.

Another way of understanding the relative roles of risk, economic, and technical factors is to consider the levels of protection authorized by the different statutes. These are summarized in Exhibit 15. In several instances, statutes direct the setting of "tolerances", for example, consistent with protection of the public health; if a zero-tolerance or ban is not authorized, some level of risk will result, as for tolerances established for carcinogens. This should be contrasted with provisions allowing for a margin of safety which have been called "essential to any health-related

EXHIBIT 14

OVERVIEW OF STATUTORY RISK AND ECONOMIC CRITERIA

RISK-BASED PROVISIONS	PROVISIONS INCLUDING ECONOMIC FACTORS
*TSCA §4(a)	*TSCA §4(b)
TSCA §5(b)(4)(A)	TSCA §6
*CWA §307(a)	*CWA §307(b)
CWA §311	---
*SDWA §1412(b)(1)	*SDWA §1412(b)(3)
SDWA §1421	---
RCRA §3001	---
RCRA §3002-4	---
FIFRA §25(c)	FIFRA §3, §6
CAA §108, §109	CAA §110
*CAA §111(b)	*CAA §111(a)
CAA §112(a), (b)	---
---	CAA §157
*CAA §202(a)(1)	*CAA §202(a)(2)
---	CAA §211(c)
*CAA §231(a)	*CAA §231(b)
CERCLA §102	Elsewhere in CERCLA
---	OSHA §6(b)(5)
FDCA provisions except §409	FDCA §409
FHSA, PPPA	CPSA

---

* "Matched pairs" combining a risk-based designation provision with cost-sensitive standard-setting (or compliance) provision.

EXHIBIT 15

LEVEL OF PROTECTION AFFORDED BY CHEMICAL CONTROL LAWS

TSCA §6(a)	"To protect adequately against [unreasonable risks] using the least burdensome requirement"
CWA §307(a)	"an ample margin of safety" (§307(a)(4)) through applying Best Available Technology (BAT) economically achievable (§307(a)(2))
SDWA §1412	as close to the Maximum Contaminant Level (MCL) "to the extent feasible ... (taking costs into consideration)" §1412(a)(2)
MPRSA	no unreasonable degradation
RCRA	"necessary to protect human health and the environment" (§§ 3002-4)
FIFRA	no "unreasonble adverse effects"
CAA §109	"adequate margin of safety"
CAA §112	"ample margin of safety to protect the public health" §112(b)(1)(B)
CAA §211	"ample margin of safety"
OSHA	"adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity" §6(b)(5)
	"reasonably necessary or appropriate to provide safe or healthful employment ..." §3(8)
DOT/HMTA	"necessary or appropriate"
DOT/USCG	"necessary to prevent/protect ..." FWSA 33 USC §1225
	"increased protection against hazards" through application of Best Available Technology unless undue economic impacts would result "which are not outweighed by the benefits" BFCLA
CPSA	"reasonably necessary to prevent or reduce an unreasonable risk of injury"

environmental standards if a reasonable degree of protection is to be provided against hazards which research has not yet identified."[81]

Language authorizing a margin of safety in agency standards has been interpreted as allowing greater discretion for both designation and standard-setting. In the case of the Clean Water Act, where the "will cause" language seems to tolerate less uncertainty than a "may" formulation, the mandate to provide a margin of safety was the basis for a ruling upholding EPA's use of information about more chlorinated PCBs as the basis for regulating less chlorinated PCBs (about which little was known). This decision upheld EPA's authority to draw inferences from available data on related substances without requiring proof of causation for each distinct chemical even where the statutory criteria used the unconditional word "will."

---

[81] S. Rep. No. 91-1196, Clean Air Act Legislative History.

IV. REGULATORY ANALYSIS

OVERVIEW

There are two different ways that chemical substances can be designated and regulated. One approach is to identify and list specific chemical substances. The other approach is to identify the harmful characteristics or effects which would qualify a chemical for regulation, leaving it up to private industry to determine which substances have such characteristics or effects. While each approach has particular advantages and problems, the reader should remember that regulatory programs frequently use both approaches (e.g., RCRA, DOT, FIFRA).

As will be seen, analyzing the specific substances which have been designated is much more difficult than analyzing the hazard classifications established by regulation. For a variety of reasons, it was not feasible to conduct a meaningful, in-depth analysis of all the regulations designating chemical substances. In addition to the absolute numbers of substances involved, other factors include:

- differences in statutory criteria for designation
- variations in the level of hazard presented by the same substance in different media
- inconsistent use of identifiers and naming conventions
- varying priorities among the different regulatory programs
- varying levels of scientific uncertainty regarding risk potential of chemicals

Therefore, the analysis of chemical substances designated by name for regulation by January 1, 1981, takes the form of a discussion of key issues and problems using specific examples as illustrations. The discussion is not exhaustive. In most cases, the examples used were derived from the creation and review of a "matrix" which collects the various substances designated. The development of the matrix is described in Volume 4 along with the coding system used. However, specific findings are discussed here as well.

In contrast, the analysis of hazard classifications and associated testing requirements is more comprehensive. Again, only hazard classifications proposed by January 1, 1981 are included, with the exception of the OSHA labelling standard which was both proposed and withdrawn during January of 1981; it is included in the analysis for information only. Testing requirements which are part of hazard classifications are analyzed; however, many other specific testing standards do exist although they do not fall within the scope of this contract.

ANALYSIS OF DESIGNATED CHEMICALS

All regulated chemicals are designated in one way or another. As part of this study, ICF developed a chemical designation matrix to list those substances designated by name in all the agency regulations reviewed. Together with the analysis of hazard classes, the matrix can be used as a starting point to identify possible gaps, conflicts, and inconsistencies. Here we review the key findings derived from the development and analysis of the matrix.

There is a variety of reasons for the designation of chemical substances for regulation, all dependent upon the statute and agency involved. The matrix demonstrates the outcome of agency actions as of January 1, 1981. See Exhibit 16. The matrix also demonstrates significant designation problems. Different naming conventions, incomplete and overlapping chemical groups, and different treatment of compounds and mixtures all make it very difficult to follow one substance through several regulations. These problems are discussed in more detail below in the following order:

- Overview
- Naming Conventions and Synonyms;
- Designation of Chemical Groups;
- Designation of Compounds; and
- Designation of Mixtures and Concentrations.

WHAT THE MATRIX SHOWS: AN OVERVIEW

The primary factors that determine which substances are designated are the regulatory authority embodied in statutory risk criteria and the available scientific evidence. Thus, it is difficult to make analytical inferences from the matrix. Just because a substance is listed does not mean it is unsafe in all uses or exposures. The use of or the environment affected by a particular substance may determine its classification. For example, a chemical in food dyes may be classified as hazardous, whereas the same chemical used in pesticides may not be. Also the assumptions that agencies make concerning risk assessment are likely to vary. These assumptions concern such issues as dose relationships, margins of safety, and models of data extrapolation, and may affect which chemicals are designated as hazardous. Finally, the manner in which agencies view exposure levels to substances may vary. Some agencies may consider the effects of chemicals as additive (e.g., FDA); in this case, exposure to several chemicals would be considered as one large hazardous exposure. Other agencies consider the effects of chemicals individually, as if humans were exposed to chemicals in a vacuum.

In addition to different risk criteria and available scientific knowledge, there are other reasons why it is difficult to use the matrix to assess gaps and inconsistencies in designation. For example, in implementing

EXHIBIT 16

SOURCES OF DESIGNATED CHEMICAL SUBSTANCES

ID in Matrix	Statute	Regulations[1/]
FWPCA	Federal Water Pollution Control Act	
§307	Toxic Pollutant Effluent Standards	40 CFR 129
§311	Designation of Hazardous Substances and Reportable Quantities	40 CFR 117.3 40 CFR 116.4
CAA	Clean Air Act	
	§108 Criteria Pollutants	40 CFR 50
	§111 New Source Performance Standards	40 CFR 60
	§112 Hazardous Air Pollutants	40 CFR 61
	§202 Motor Vehicle Emissions	40 CFR 85
	§211 Fuels and Fuel Additives	40 CFR 80
	§231 Aircraft Emissions	40 CFR 87
SDWA	Safe Drinking Water Act	
	§1412 Primary & Secondary Drinking Water Standards	40 CFR 141
RCRA	Resource Conservation and Recovery Act Hazardous Wastes	40 CFR 261, Appendix VIII
TSCA	Toxic Substances Control Act	
	§4 Testing Requirements	45 FR 48554
	§5 Premanufacture Notification	45 FR 28805
	§6 Limitations on Use	40 CFR 761 40 CFR 762 44 FR 60061
FDA/FIFRA	Food & Drug Administration/Federal Insecticide, Fungicide & Rodenticide Act (EPA)	
	Pesticides with Established Tolerances	40 CFR 180
FIFRA	Federal Insecticide, Fungicide & Rodenticide Act (EPA)	40 CFR 162.30 40 CFR 162.11 40 CFR 170
MPRSA	Marine Protection Research & Sanctuaries Act (EPA)	40 CFR 227
CPSA	Consumer Product Safety Act (CPSC)	16 CFR 1303.2 16 CFR 1304 16 CFR 1401 45 FR 39434

EXHIBIT 16 (Continued)

SOURCES OF DESIGNATED CHEMICAL SUBSTANCES

ID in Matrix	Statute	Regulations[1]
PPPA	Poison Prevention Packaging Act (CPSC)	16 CFR 1700.14
FHSA	Federal Hazardous Substances Act (CPSC)	16 CFR 1500.12-17
OSHA	Occupational Safety & Health Act (OSHA)	
	§6b	29 CFR 1910.1000
	§6a	29 CFR 1900.1000
HMTA	Hazardous Materials Transport Action Act (DOT)	49 CFR 172.101
FDA	Food and Drug Administration[2]	21 CFR 510

---

[1] This exhibit contains general references showing where the substances are listed. However, the matrix contains all rules proposed or promulgated by the agencies as of January 1, 1981, so there are many other Federal Register notices used to update and revise the CFR references.

[2] The matrix lists for the FDA the 24 substances which have been banned under the Food, Drug and Cosmetic Act, not the thousands of substances for which tolerances have been established by regulation.

their legal authorities, agency programs may vary both in priorities and in total resources available for implementation.

Beyond this, provisions for variances, exceptions, and exclusions may result in potential real-world inconsistencies that would not be at all apparent from a review of the matrix. A good example of this is the reporting requirement for hazardous polluting substances established under Section 311 of the Clean Water Act codified at 40 CFR 117. The exceptions for (1) discharges from facilities with National Pollutant Discharge Elimination System (NPDES) permits and (2) discharges from other publicly-owned treatment works (POTWs) allow significant opportunities for gaps or inconsistencies in reporting. A discharge of a hazardous substance excluded from Section 311 coverage may exceed the Part 117 reportable quantity for that substance, and yet, not be controlled under other regulatory or statutory provisions. This allows the possibility of discharges which exceed Part 117 reportable quantities and "may be harmful." In addition, not all the hazardous polluting substances designated under Section 311 have also been designated as toxic effluents under Section 307.

Despite the difficulties in comparing the designation of hazardous substances, the form of the matrix emphasizes several important aspects of the way agencies designate chemicals.

- Naming conventions and definitions are not always standardized and may conflict.
- Some regulations often do a poor job of identifying synonyms for listed substances.
- Much inconsistency exists in the use of generic terms designating groups of substances.
- The regulations are either vague or in conflict with respect to the designation or inclusion of compounds, isomers, etc.
- Treatment of mixtures is limited and ad hoc.

Examples appear throughout the matrix and demonstrate the variety of policies that exist for designating substances. Some selected examples (e.g. arsenic compunds, PCBs) are included in the analysis.

Besides demonstrating how chemicals are designated, the matrix also demonstrates which chemicals are designated most often. Certain substances stand out because they are designated under many regulations. These substances, because of their hazardous nature, prevalence, potential threat, or even notoriety, are designated under seven or eight statutes or provisions of statutes. Those appearing under eight columns include:

- lead
- endrin
- benzene
- arsenic
- asbestos

Those appearing under seven columns consist of:

- acrylonitrile
- aldrin
- cadmium
- chlordane
- DDT
- heptachlor
- vinyl chloride
- mercury

Several of these are pesticides (endrin, aldrin, heptachlor, and DDT), while others (mercury, lead, cadmium, vinyl chloride, etc.) are used in a variety of applications.

It is important to emphasize that simply because a substance is not listed does not mean that it is necessarily safe in all uses or not a public health problem. For example, at the time the Interim Primary Drinking Water Regulations were proposed, EPA had recently cancelled all use of DDT and suspended the major uses of Aldrin/Dieldrin, exercising its authority under FIFRA.[52] MCLs for these substances were not proposed, therefore, until ongoing research could determine the extent to which these chemicals might continue to persist in drinking water. Similarly, the proposed MCLs for chlordane, heptachlor, and heptachlor epoxide were deleted from the Final Interim Regulations because EPA was involved at the time in suspension and cancellation hearings for these pesticides.[53] Thus, because of the many confounding factors affecting the presence or absence of a chemical designation, a comprehensive analysis of "gaps" would not be meaningful.

NAMING CONVENTIONS AND SYNONYMS

A basic problem in comparing any kind of chemical designations is the number of nomenclature systems presently used by different industries, government, and researchers.[4] The system of nomenclature (or combination of systems) used in designating chemicals depends on: (1) when the regulations were promulgated, since naming conventions have evolved over the years, and (2) to what group of people the regulations are targeted. HMTA regulations need to be understood by the transportation industry, which is accustomed to one set of names and numbers, while FIFRA regulations are used by the chemical industry and by users, like farmers, both of which employ different naming conventions. The most common naming systems, all of which are seen in the matrix under different regulations, include the following:

---

[52] See the preamble to the proposed interim drinking water regulations, 40 FR 11991 (March 14, 1975), and the review of Safe Drinking Water regulations in Volume 2.

[53] 40 FR 59578.

- IUPAC System: This system, most recently developed, names compounds on the basis of their molecular structure. A set of rules is applied to give a unique name to every compound, including structural and steriochemical isomers. This system is the most specific and complete, because once a simple set of rules are understood, any compound can be given one specific name. This system can be recognized by the use of numbers in parentheses (e.g. tetrachloroethane (1, 1, 2, 2-)), and the use of certain suffixes and prefixes (e.g. -one, -ol, eth-, prop-). What is gained by clarity, in this system, however, is often lost in long, cumbersome names that may be difficult to read, remember, or understand. For this reason, this newest system has not been taken up by many laymen and industries who still use the systems described below.

- Common Naming System: Chemists have often employed a "common" name to refer to a widely used compound. Although common names reveal the true chemical formula of a compound, and are shorter than IUPAC names, they are more ambiguous, and consequently were more difficult to match up with chemical groups and synonyms when constructing the matrix. Common names, nonetheless, are widely used and can be recognized (at least the simpler ones) in the matrix by the use of a series of groups. For example, heptanone (3-) in the IUPAC system has the common name of ethyl butyl ketone, where all three words refer to different chemical groups. Common names have been in use in this country much longer than the IUPAC system. The regulations, therefore, tend to use these names quite often, especially with widely used chemicals.

---

[4] Besides nomenclature systems, these are also several numerical systems (not included in the matrix) for naming chemicals. Examples include the United Nations System (U.N.), Chemical Abstract Service (CAS) numbers, and the Standard Transportation Commodity Code (STCC) system.

- Chemical Abstract Service, which also designates every chemical by a CAS number, utilizes their own system of nomenclature. The system primarily employs IUPAC rules and names except for a few deviations. To ensure that chemicals are properly identified, CAS publishes several references, including the Chemical Index Guide and the Registry Handbook of Common Names that cross-reference CAS, IUPAC, and common names. Most of the CAS names would be included in the matrix since they usually correspond to IUPAC names.

- Generic Names: A generic name makes it easy for a layman to identify a particular compound or product. These names are especially appropriate when it is the layman who will be dealing with the chemical, such as designating consumer products for special labeling. An example of a generic name would be rubbing alcohol. This name can be easily understood by those who will be using it (consumers). However, ethyl alcohol, the "common" name, and ethanol, the IUPAC name, would not be. Generic names are also used for some mixtures, and for products that have certain uses or sources, (e.g., "mineral spirits," "coal tar dyes") instead of distinguishable chemical formulations.

- Brand Names: Pesticides are often designated by brand name (aldrin, mirex, parathion) because they (1) are a mixture of isomers or active ingredients, (2) are often very long, complicated names, and (3) are protected by trade secrets. Some pesticides are identified by both the active ingredient and the brand name (Ventox, Fumigrain = acrylonitrile), others (Aldrin, Baam) by just the brand name, and others by just the active ingredient (DDT, TDE, etc.). Even with an extensive knowledge of chemistry, it is difficult to match up different formulations and trade names with the active ingredients that might be designated under other statutes. Therefore, some substances may be listed unknowingly twice in the matrix: once under the brand name, and once under the chemical name.

The matrix is useful in this case because it indicates the names that are used by each agency, for each chemical, and under each naming system.

No regulations use one naming system exclusively, although there are some trends. FWPCA §311, for instance, tends to include both the IUPAC and common name, with one as a synonym. HMTA and RCRA, on the other hand, primarily use common names, but not exclusively. The source of the substance often determines the name that is used. Any widely used industrial chemical has usually been referred to by a common name for years. A pesticide that has been developed recently may have an IUPAC name or a shortened version of an IUPAC name. (For example, 2-4-D acid = 2, 4 dichlorophenoxyacetic acid). In other words, the actual name by which the substance is referred to depends on a variety of factors, all of which make it difficult to utilize one system across the board.

The variety of naming conventions would not necessarily be a significant problem if the regulations themselves provided suitable cross-references to synonyms. They do not. In fact, tracing the regulatory status of a particular chemical is often quite difficult. FWPCA §307 regulations do not generally identify synonyms while FWPCA §311 regulations do list all synonyms of each substance, whether there are two names or five for one chemical substance. HMTA regulations usually list only one name, except in a few instances where two names are listed. RCRA regulations list some synonyms, but not all of the time. FIFRA regulations often do not adequately cross-reference brand names to chemical names. This problem gets compounded by the alternative ways that chemicals are designated in groups, discussed next.

DESIGNATION OF CHEMICAL GROUPS

The use of generic categories further complicates the analysis of designation. Designation of a class of chemicals (e.g., chlorinated benzenes) can subsume many individual substances. Although the Interagency Testing Committee can include no more than 50 entries on its recommended priority testing list, for example, use of chemical classes means that the actual number of chemicals recommended to EPA expands to over a thousand. On the other hand, there may be good reasons for designating chemical classes as opposed to individual substances. For example, establishing a drinking water standard for total trihalomethanes rather than for specific compounds is required by available testing and analytic constraints. The problems arise where agencies define or interpret designated chemical groups in different ways.

Where chemical classes are used instead of specific substances, opportunities for inconsistencies or conflicts can arise. MPRSA dumping permits are issued by two separate organizations that each have discretion in interpreting criteria for permit approval. To assure consistency, more specific designation of limitations and allowances on ocean dumping of identified chemicals (e.g., organohalogens) may be advisable.

Another major problem arose in the attempt to cross-reference groups of chemicals between regulations. In general, elements such as chlorine and arsenic, that appear in many compounds and forms (chlorine, chlorides, chloric, etc.) are not clearly designated in the regulations even though each form of the element may present entirely different hazards. A good example is provided in Exhibit 17, which outlines the designation of arsenic compounds in proposed or final federal regulations. Confusion arises from the designation of groups and substances within that group. For example, HMTA designates both inorganic arsenicals and a number of arsenic compounds such as arsenic bromide, arsenic sulfide, and arsenic trioxide, as hazardous. All of the arsenic compounds that are listed would normally be considered inorganic

EXHIBIT 17

DESIGNATION OF ARSENIC AND ARSENIC COMPOUNDS IN THE REGULATIONS

Statute	Designation	
FWPCA		
§307	Arsenic and compounds	
§311	Inorganic arsenicals	Arsenic acid anhydride
	Calcium arsenate	Arsenic oxide
	Calcium orthoarsenate	Arsenic trichloride
	Arsenic disulfide	Arsenic chloride
	Red arsenic sulfide	Arsenous chloride
	Arsenic pentoxide	Butter of arsenic
CAA		
§112	Arsenic, Inorganic	
SDWA	Arsenic	
RCRA	Arsenic and compounds, n.o.s.	
	Arsenic pentoxide	
	Arsenic acid	
	Arsenic trioxide	
FDA/FIFRA	Inorganic arsenicals	
	Calcium arsenate	
FIFRA	Inorganic arsenicals	Calcium arsenate
	Ammonium arsenite	Copper acetoarsenite
	Arsenic	Sodium arsenate
	Arsenic acid	Sodium arsenite
	Arsenic pentoxide	Sodium pyroarsenate
	Arsenic trioxide	
OSHA		
§6a	Arsenic (organic)	
	Inorganic arsenicals	
	Calcium arsenate	
§6b	Arsenic, Inorganic	
HMTA	Arsenic	Arsenic iodide
	Inorganic arsenicals	Arsenic pentoxide
	Arsenic bromide	Arsenic sulfide and a chlorate, a mixture
	Arsenic chloride (arsenious)	Arsenic trichloride
	Arsenic disulfide	Arsenic trioxide
	Arsenic sulfide	Arsenic trisulfide

arsenicals. If "inorganic arsenicals" is meant to include all inorganic arsenic compounds, why are some listed, and some not? If not, then what does inorganic arsenicals include? See question marks in Exhibit 18, drawn from the chemical designation matrix.

The point here is that the regulations are not always developed or used by personnel trained in general chemistry, much less in specialized fields. Without specific knowledge of the general meaning of these terms, and the way agencies use them, it is difficult to identify particular chemicals in designated groups.

Another problem arises when agencies give categories special definitions that do not clearly follow the category name. For example, under OSHA §6b, "inorganic arsenic" includes "copper aceto-arsenate, and all inorganic compounds containing arsenic except arsine, measured as arsenic" (29 CFR 1910.1018(b)). Copper aceto-arsenate, in a strict sense, is not an inorganic chemical, because it contains organic carbon. Arsine, on the other hand, would normally be considered an inorganic arsenic compound. When comparing the OSHA designation with FWPCA §311, which also covers inorganic arsenic compounds, it is clear the latter does not utilize the same definition as OSHA.

Besides the overlaps and conflicting names, test methods may determine which compounds are included within a designated category. Because agencies may not require the same tests, this could lead to different classifications. In any event, deciphering the list of arsenic compounds requires not only in-depth knowledge of chemical structure in general, but, specifically, how different agencies define and group different structures.

Where regulations are unclear, general chemical knowledge provided the basis for categorizing and cross referencing chemical groups. It is important to remember that there may be agency policies--unrecognized in the matrix--that categorize chemicals differently, or deal with some substances within the category in a different manner.

DESIGNATION OF COMPOUNDS

Exhibit 17 also points out another basic uncertainty in the definition (or lack of a definition) of the word "compound". An agency designates a chemical, such as arsenic, as hazardous, and then may or may not list or otherwise include its compounds, isomers, hydrates, or mixtures. On the one hand, the regulations may specify that the element or compound specifically listed includes other forms. For instance, under FWPCA §311, the designation of a hazardous substance includes "any isomers and hydrates, as well as solutions and mixtures containing these substances" (40 CFR 116.4). Under FPWCA §307 and SDWA, the designation of compounds simply includes organic and inorganic compounds. In order to match up these chemicals with HMTA or the CAA designations, which only include inorganic arsenic compounds, every arsenic compound must be evaluated and placed in one of these groups.

EXHIBIT 18

DESIGNATION OF ARSENIC AND ARSENIC COUMPOUNDS IN THE MATRIX

	FWPCA §311	FWPCA §307	CAA	SDWA	RCRA	TSCA	FDA/ FIFRA	FIFRA	MPRSA	CPSA	PPPA	FHSA	OSHA §6b	OSHA §6a	HMTA	FDA
arsenic	Z	Z/NR		X	Y		Z	Y					Y	Z	X	
arsenic, inorganic (partial list)	Z	Y/NR	X/NR	Y	Y		Z	Z					X	Z	S	
ammonium arsenite	Y	Y/NR		Y	Y		Y	X					Y	Y	Y	
arsenic acid	Y	Y/NR		Y	X		Y	X					Y	Y	X	
arsenic pentoxide	X	Y/NR		Y	Y		Y	X					Y	Y	X	
arsenic trioxide	Y	Y/NR		Y	Y		Y	X					Y	Y	X	
calcium arsenate	X	Y/NR		Y	Y		X	X					Y	X	[illegible]	
calcium orthoarsenate	X	Y/NR		Y	Y		S	S					Y	U	U	
copper acetoarsenite	?	?		?	?		?	X					Y	Y	Y	
inorganic arsenic	?	Y/NR		Y	Y		?	?					X	?	?	
inorganic arsenicals	X	X/NR		Y	Y		X	X					Y	X	X	
sodium arsenate	Y	Y/NR		Y	Y		Y	X					Y	Y	Y	
sodium arsenite	Y	Y/NR		Y	Y		Y	X					Y	Y	Y	
sodium pyroarsenate	Y	Y/NR		Y	Y		Y	X					Y	Y	Y	
arsenic acid **See** arsenic, inorganic																
arsenic acid anhydride **See** arsenic pentoxide																
arsenic and compounds	Z	X/NR		S	Y		Z	Z					Z	Z	Z	
arsenic and compounds, NOS	?	?/NR		?	X		?	?					?	?	?	
arsenic bromide	Y	Y/NR		Y	Y		Y	Y					Y	Y	X	
arsenic chloride **See** arsenic trichloride																
arsenic chloride (arsenious) **See** arsenic trichloride																
arsenic compounds (as As) ((organic))		Y/NR		Y	Y									X		
arsenic disulfide	X	Y/NR		Y	Y		Y	Y					Y	Y	X	
arsenic sulfide	S	Y/NR		Y	Y		Y	Y					Y	Y	X	
red arsenic sulfide	X	Y/NR		Y	Y		Y	Y					Y	Y	S	
arsenic iodide	Y	Y/NR		Y	Y		Y	Y					Y	Y	X	
arsenic oxide **See** arsenic pentoxide																
arsenic pentoxide	X	Y/NR		Y	X		Y	Y					Y	Y	X	
arsenic acid anhydride	X	Y/NR		Y	S		Y	Y					Y	Y	U	
arsenic oxide	X	Y/NR		Y	S		Y	Y					Y	Y	U	

With one exception discussed below, the interim primary drinking water regulations for inorganic chemicals (see 40 CFR 141, Subpart B) do not specify whether a standard refers to a contaminant only in its elemental form or as it is found in certain or all compounds. Clearly, such a distinction is important, though it is never addressed in the Preamble or body of the regulations. The only guidance EPA gives at all on this issue is in the prescribed test and measurement procedures. For each contaminant, EPA specifies the procedure which must be used by state authorities to test for its presence in drinking water supplies. According to an EPA official, these procedures identify the contaminant in all forms, elemental and compound, in which it may be present.[11] Mercury, however, is defined in the regulations as mercury and "mercurial compounds" specifically, for reasons that are not made clear. Moreover, the interim regulations for radionuclides and organic chemicals are extremely specific in defining the exact compounds to which they refer. EPA appears not to have adopted a uniform designation approach and format in this instance.

On the other hand, regulations may refer to chemicals "not otherwise specified," (n.o.s.) that differentiate between those that are listed separately, and those included within a group. One problem that arose with designation under RCRA is that it uses the "n.o.s." designation even if there are no other compounds listed, which leads to a confusing search for other compounds. HMTA is even less specific. The DOT hazardous materials table lists an element, and then only some of its compounds, without an n.o.s. specification at all. In the matrix, therefore, the designation of an element under HMTA did not automatically trigger the inclusion of its isomers or compounds.

DESIGNATION OF MIXTURES AND CONCENTRATIONS

Mixtures also make it more difficult to compare the designation of particular substances under different statutes. Certain mixtures may pose greater hazards than the constituents by themselves because of chemical reactions between constituents. On the other hand, mixtures that contain only trace quantities (i.e., low concentrations) of hazardous constituents, or that neutralize the hazardous attributes of the constituents, may not be hazardous at all.

Because it is impossible to predict which hazardous substances will be mixed together, most agencies tend to list the individual element or compound, except where mixtures can be predicted (i.e., specific waste streams, products, etc.). A further problem reflects inconsistent definitions of the designated mixtures. Finally, the designation of mixtures using generic names (e.g., shellac, rubber curing compounds) makes it impossible to identify all regulated constituents.

---

[11] Personal communication with E. Bellack, EPA, on October 2, 1980.

Under FWPCA §311, the designation of a hazardous substance includes mixtures containing the substance where "mixture" means "any combination of two or more elements and compounds." (40 CFR 116.4). However, in determining reportable quantities for spills, mixtures are not included except where a component is both a designated substance and is discharged in a quantity exceeding its reportable quantity (RQ). This distinction avoids the mandatory reporting of spills of mixtures that contain low concentrations or amounts of designated hazardous substances.

Both toxic effluents and hazardous wastes regulations provide for identifying chemicals that may be disposed of either as part of waste streams (i.e., mixtures) or as discrete substances. The toxic effluent list established under FWPCA §307 identifies only compounds or elements but applies to discharged mixtures by regulating the concentration of designated toxic effluents permitted to be released. RCRA regulations list both specific substances as well as waste streams (i.e, mixtures) as hazardous wastes; however, standards for hazardous wastes may not apply where the concentrations of listed wastes can be shown to be non-hazardous.

Similarly, not all designations identify minimum concentrations for listed substances. The HMTA regulations do the best job of this. Other regulations handle concentrations through a general policy, if the issue is discussed at all. Although the EPA regulations for reporting spills of hazardous polluting substances do not specify minimum concentrations, the companion rules adopted by DOT do; this represents an inconsistent designation.

The application of DOT's incident reporting regulations to mixtures and solutions containing hazardous substances is illustrated by the inclusion of the following table in 49 CFR 171:

RQ Pounds	RQ Kilograms	Concentration by Weight	
		Percent	PPM
5,000	2,270	10	100,000
1,000	454	2	20,000
100	45.4	0.2	2,000
10	4.54	0.02	200
1	0.45	0.002	20

If the reportable quantity for a certain hazardous substance is 100 pounds, less than a 0.2 percent concentration by weight of that material in a mixture or solution would NOT be subject to DOT's regulations. Further, the 0.2 percent or greater concentration by weight of that material must be contained in one package to be subject to DOT's regulations. Thus, the DOT regulations are closely related, but not identical to the Part 117 regulations for discharges of hazardous substances.

The designation of PCB's is an interesting case because PCB's are not produced in pure form except for research purposes. Rather, they exist as complex mixtures of PCB molecules which are typically described by the percent chlorine content by weight. Most of the regulations give little guidance as to which mixtures are covered, referring to "polychlorinated biphenyls" without any more detailed description.[56] See Exhibit 19. Although the definition seems to encompass all PCB chemicals, there is some ambiguity as to whether monochlorinated biphenyls (MCB's) are included.[57] The few rules which do provide definitions, however, are quite consistent. Regulations promulgated under FWPCA and TSCA both specify as PCB's any compound or "mixture of compounds composed of the biphenyl molecule which has been chlorinated to varying degrees."[58]

HAZARD CLASSIFICATION AND TESTING REQUIREMENTS

Many regulations designate not only specific chemicals, but also characteristics of chemicals, as hazardous. The use of characteristics or classifications has several advantages. First of all, under these rules, it is usually the responsibility of industry to test specific chemicals and mixtures of chemicals for dangerous properties. Secondly, this "generic approach" results in far more comprehensive coverage than listing individual substances, since all materials--not just those materials that the agencies are aware of and have the resources to analyze--must be evaluated against the hazard criteria. Finally, specifying general types of dangers also provides structure to the regulations. Labeling and handling requirements are frequently organized according to hazard so that substances that pose similar risks are treated in similar fashion. In this way, hazard classes may determine how, as well as which chemicals are regulated.

In establishing generic hazard classifications agencies have set up (1) exact, testable categories, (2) more general descriptive definitions and, (3) in some instances, no definitions at all. Precise categories that are delineated by standard physical, chemical or biological tests, such as flash-point ranges, appear to be the most useful. In many cases, however,

---

[56] Although they fail to provide definitions, the regulations promgulated under FDA and Section 311 of FWPCA do refer to the trade name Aroclor. See Exhibit 19.

[57] MCB mixtures can be produced by reducing the amount of chlorine available for reaction with the biphenyl compound.

[58] This specific definition is provided in the regulations promulgated under Section 307 of FWPCA. Slight differences in the wording of the other regulatory definitions are not significant.

EXHIBIT 19

DEFINITIONS OF PCB's

Statutory Authority	Definition
TSCA	"... any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees or any combination of substances which contains such substance" (40 CFR 761.2(s)).
FWPCA, Section 307	"... a mixture of compounds composed of the biphenyl molecule which has been chlorinated to varying degrees" (40 CFR 129.4).
FWPCA, Section 311	"for convenience of the user" only, CAS Registry #1336363 and the synonyms Aroclor and Polychlorinated diphenyls are provided (40 CFR 116.4).
OSHA	referred to as "chlorodiphenyl" (29 CFR 1910.1000).
FDA	"... a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States)" (21 CFR 109.15, 500.45, and 509.15)
FMIA, EPIA, FEPIA	none provided (see MPI Directive 917.1)
HMTA	none provided (see 45 FR 34560).

there are no reliable or comprehensive tests that cover all of the substances, that, for proper handling, should be grouped in one category. In those cases, agencies have utilized descriptive definitions that require judgment and interpretation; this also causes problems.[59/]

The different agencies, mandates, and methods have resulted in a myriad of testing requirements, classifications, test levels, and permit conditions that regulated industry must satisfy. Some attempts have been made to coordinate regulations, for instance between EPA under RCRA and DOT under HMTA. However, inconsistencies exist both among and within different agencies' programs. One important reason for this is the fact that each regulation controls a different type of exposure--a characteristic which is hazardous in one medium (e.g., consumer products) may not be deemed hazardous in another for which public exposure is smaller (e.g., solid waste).

Of course, existence of a logical justification does not alleviate industry's problem in trying to comply with conflicting hazardous substance classifications and testing requirements. Industry must determine which substances and which instances require testing. If the hazardous substance is dealt with by classification, inconsistent definitions of hazard classes and testing requirements can force firms to reevaluate test data, or to perform expensive new tests altogether. In addition, conflicting definitions eliminate the simplicity which, after all, is one of the main reasons for the categories in the first place.

The analysis presented here shows the kinds of classification used and what tests must be satisfied. Included are the hazard categories (and associated testing requirements), if any, that have been established by seven different agencies under nineteen separate statutes, as shown in Exhibit 1. In general, there are different approaches to selecting hazard classes, defining them with reference to specific tests, and specifying the test results that must be satisfied.

In order to better understand both the causes and effects of the inconsistencies, it is essential to analyze each type of hazard individually. The analysis covers the following generic hazard classifications:

- Toxic Substances
- Fire Hazards
- Corrosive Hazards
- Reactive Hazards
- Radioactive Hazards
- Other Hazard Classifications.

[59/] See, for example, DOT's Advance Notice of Proposed Rulemaking, Definition of Flammable Solid, 46 FR 25492 (May 7, 1981).

TOXIC SUBSTANCES

Overview. The term "toxic substance" encompasses materials which produce a wide variety of adverse effects, including neurological damage, blood disorders, birth defects, and cancer.[60] This diversity makes it very difficult to construct a comprehensive screening procedure--especially in light of the long period of time required for some of the effects to become evident.

Agencies must make decisions about the regulation of toxic subtances, basing those decisions on 1) criteria that are mandated in the statute, and 2) whatever data, tests, or descriptions are available or possible to obtain. Because of the diversity of toxic effects, levels of information on these effects, and types of exposure to toxic substances, the toxicity of a substance is often dealt with case-by-case through listing. However, there are some quantifiable tests and data that narrow the judgmental area within which the agency must make its decision.

EPA, for the most part, has used the listing mechanism to designate toxic substances. For instance, under Section 112 of the CAA, EPA has designated certain "hazardous air pollutants" (NESHAPS) primarily based on their acute or chronic human toxicity. In designating certain chemicals, EPA has utilized human studies and animal test data. The end result of these considerations, however, is not an exact, testable category of "hazardous air pollutant", or "toxic substance", but a list (over time) of specific chemicals that fit the descriptive mandate in the statute. The determination of toxicity by EPA under RCRA, TSCA, FIFRA, CAA, CWA, SDWA, MPRSA, and CERCLA follow this listing procedure. The partial exceptions to this are RCRA, FIFRA and Section 311 of CWA, all of which are discussed in more detail below.

The rules promulgated under RCRA relieve industry of the testing burden almost entirely, relying instead on the listing mechanism for designating toxic wastes. The only analysis required is the Extraction Procedure, which is designed "to identify wastes likely to leach hazardous concentrations of particular toxic constituents into the groundwater under conditions of improper management."[61] The actual specification of which constitutents are toxic is still made by EPA.

---

[60] In this section "toxic substances" refer to human (or animals used to assess human) toxic effects. Tests on aquatic animals and wildlife, and other environmental toxic effects, are discussed under "Environmental Hazards" below.

[61] 45 FR 33110 (May 19, 1980).

Certain EPA regulations under FIFRA and CWA Section 311 (Designation of Hazardous Substances) utilize toxicological data for screening purposes, rather than for classifying certain toxicological ranges as "highly toxic," "toxic", etc. Under FIFRA, acute toxicity tests are used to categorize pesticides for the purposes of labeling, classification, special packaging, and triggering the RPAR process. All of the values (Oral LD50, Dermal LD50, etc.) are shown in Exhibits 6-11 through 6-15 in the FIFRA Regulatory Review (see Volume 2). The labeling regulations, however, seem to form the basis for the other FIFRA regulations and are also the most consistent with other EPA and non-EPA programs. In the generic classifications discussed below, "FIFRA" refers to the labeling categories (I-IV) outlined in 40 CFR 162.10.

Regulations promulgated under Section 311 of the CWA to designate hazardous substances and their reportable quantities for discharge include toxicological selection criteria (see Exhibit 2-16, Volume 2). If a candidate substance meets any one of these criteria, including toxicity to aquatic flora, mammals (humans), or aquatic animals, then the substance is further examined for discharge potential. Although the aquatic toxicity levels are not used to define a generic category per se, the levels are shown for comparison purposes.

Like EPA, other agencies deal with human toxicity case-by-case. CPSC, USDA, and FDA all employ the listing mechanism, even though they may require toxicity test data to be submitted. For example, for the approval of external color additives, FDA recommends the following test data: "acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded skin, and carcinogenicity by skin application." (21 CFR 70.42). These tests, however, are not described further.

Some regulations, however, do include common toxicity cagegories and do describe toxicity tests, namely FIFRA, RCRA, HMTA, FHSA, and OSHA. However, these regulations take a more segmented approach to the designation of toxic substances, using the listing mechanism only to identify chemicals which present hazards that cannot be easily tested. For this reason, each type of hazard must be considered separately. The following types of hazards will be dealt with below:

- acute hazards
- chronic hazards

- Testing Requirements for Acute hazards: Acute toxicity can be determined fairly easily, since the effects are unmistakeable and, by definition, appear rapidly. The ease of measurement has encouraged adoption of testing requirements under RCRA, FIFRA, HMTA, FHSA, and proposed by OSHA.

The criteria for acute hazards are very similar, as shown in Exhibit 20. The most important difference readily apparent in the rules is the absence of a separate inhalation criterion for gases and vapors under RCRA, HMTA and FIFRA. It is unclear whether these materials are covered under the inhalation

EXHIBIT 20

ACUTE TOXICITY PARAMETERS

	RCRA	FIFRA	CWA §311	HMTA	FHSA	OSHA
Oral Toxicity LD50 [1]	X	X	X	X	X	X
Inhalation Toxicity (mist, dust, and fumes) LC50 [2]	X	X		X	X	X
Inhalation Toxicity (vapors and gases) LC50 [3]			X		X	X
Dermal Toxicity LD50 [4]	X	X	X	X	X	X

---

[1] Lethal dose at which 50% of the test animals expire, expressed in terms of mg/kg of body weight.

[2] Lethal concentration in air, at which 50% of the test animals expire, expressed in mg/l.

[3] Lethal concentration at which 50% of the test animals expire, expressed in ppm.

[4] Lethal dose, applied to intact or abraded skin, at which 50% of the test animals expire, expressed in terms of mg/kg of body weight.

criterion for mists, dusts, and fumes and assuming they are, to what extent the 2 mg/l and 200 ppm limits are related.

Exhibit 21 clearly shows that differing classifications have been developed to describe the same levels of toxicity. Conversely, different levels of toxicity may be described by the same classification. There are also subtle differences between the group definitions which obscure the different acute toxicity test results shown in Exhibit 23. A number of inconsistencies arise, for example, in the specification of animal test populations. The HMTA and FHSA regulations, and OSHA's proposed labeling rule grant no leeway -- oral and inhalation tests must be administered to rats weighing between 200 and 300 grams, dermal tests to rabbits weighing between 2.3 and 3.0 kilograms. The number of animals must be at least 10 and, in the case of FHSA, "sufficient to give a statistically significant result."[62] Under FIFRA, on the other hand, certain test populations are not required in the regulations. Instead, they refer to the Registration Guidelines for further explanation. [63] CWA, Section 311 Toxicological Selection Criteria (40 CFR 116.10) do not provide any recommendations for test populations, nor do the RCRA regulations at 40 CFR 261.11(a). The acute toxicity testing protocols may also prescribe different lengths of time that the test animals must be watched for adverse effects after the exposure is complete. For example, FHSA and OSHA require an observation period of 14 days, while DOT requires a period of only 48 hours. Other regulations, such as RCRA, do not spell out observation period requirements.

The regulations differ not only in the nature of the animal test populations, but also in the conditions to which those populations must be exposed. For example, the rules promulgated under HMTA and FHSA, unlike the ones proposed under OSHA, do not require inhalation toxicities to be tested to the full 2 mg/l (or 200 ppm) limit as long as "such concentration is [un]likely to be encountered by man when the substance is used in any reasonably forseeable manner."[64] In addition, the OSHA regulations require exposure periods to be extended from one hour to four "where there is difficulty maintaining a steady concentration."[65]

---

[62] 16 CFR 1500.3(c)(1)(ii).

[63] March 1980 Draft Proposed Registration Guidelines.

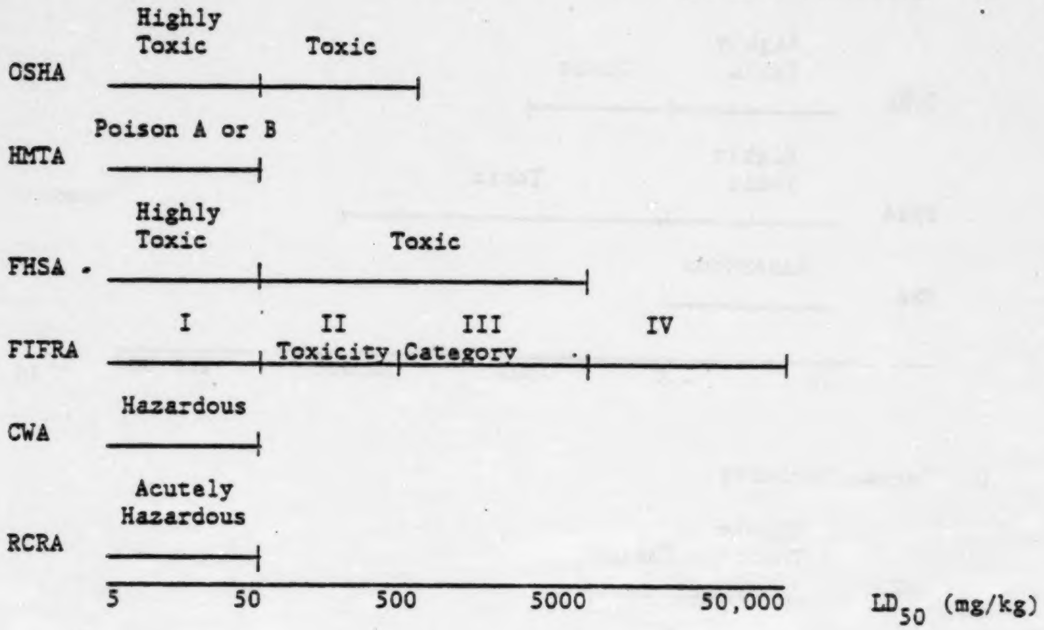
[64] 49 CFR 173.343 (a)(2) and 15 USC 1261(h)(1)(b).

[65] 46 FR 4412 (January 16, 1981) OSHA Proposed Rules on Hazards Identification, withdrawn for consideration by new administration February 12, 1981, 46 FR 12020.

EXHIBIT 21

TOXICITY TESTS

A. Oral Toxicity



B. Inhalation Toxicity (mists, dusts, and fumes)

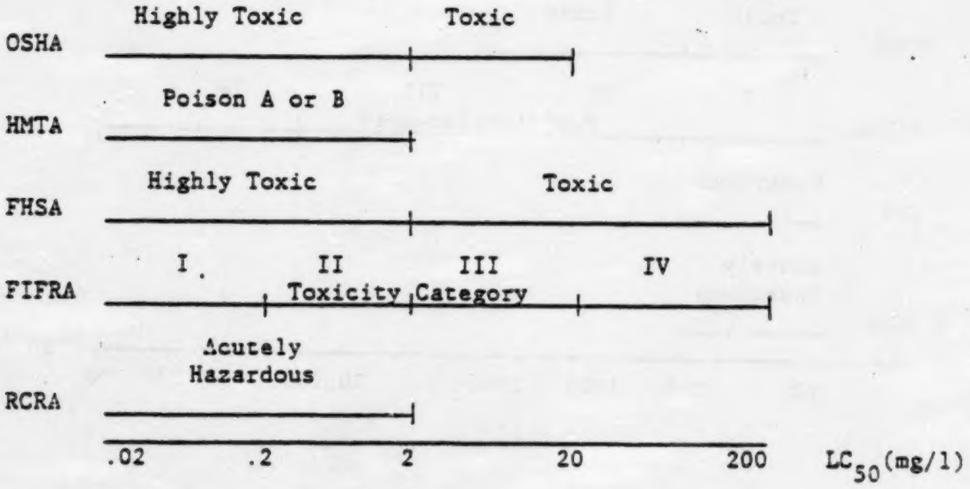
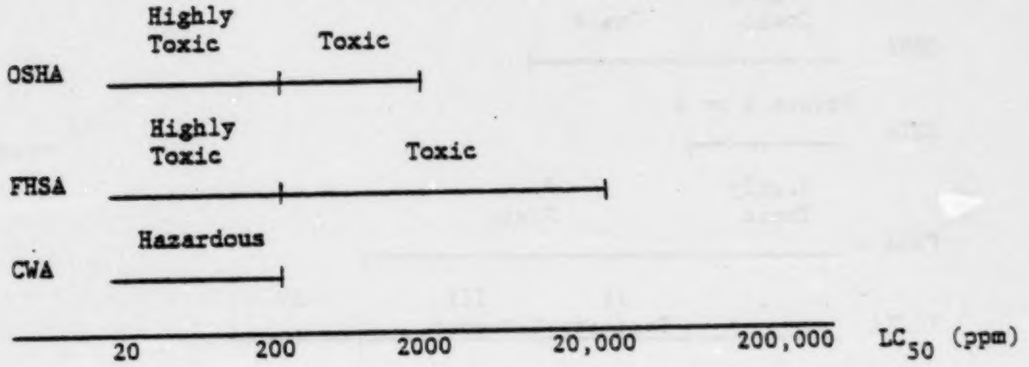


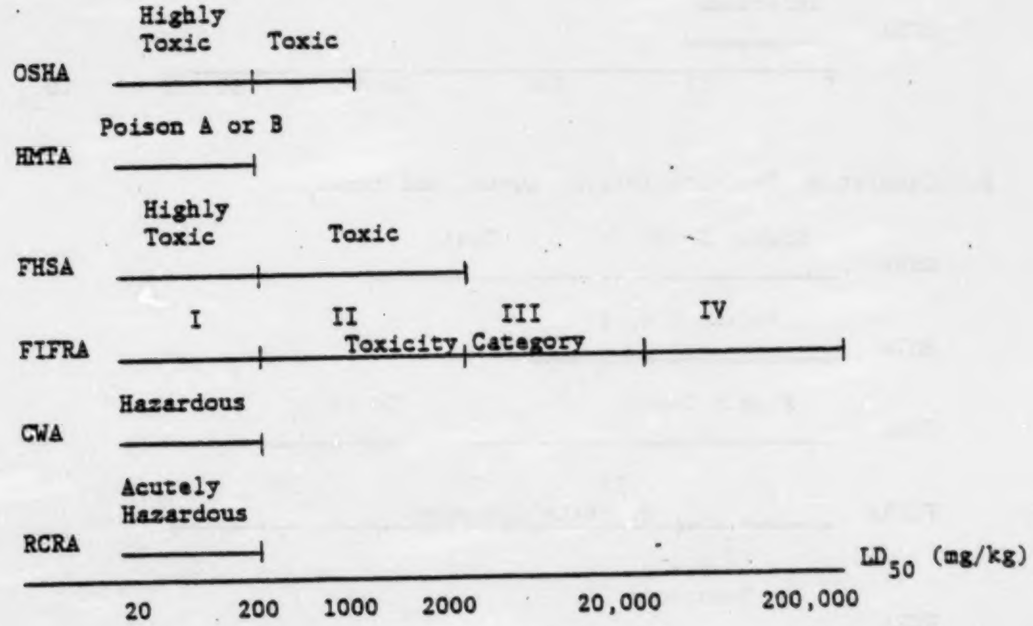
EXHIBIT 21 (Continued)

TOXICITY TESTS

C. Inhalation Toxicity (vapors and gases)



D. Dermal Toxicity



- Chronic Hazards: Chronic health effects are more difficult to quantify than acute toxicity, as explained below. The major classification under chronic toxicity is carcinogencity, however, other categories include mutagenicity and teratogenicity.

Carcinogenicity, in contrast to acute toxicity, is very difficult to determine because of a number of factors:

(1) the long-term nature of cancer development;

(2) the small proportion of populations exposed to carcinogens which actually contract the disease; and

(3) the multiplicity of possible cancer causes which can interfere with the selection of control groups and the interpretation of experimental results.

The resulting problems in establishing testing protocols have led to the adoption of listing as the primary mechanism for designating chemical carcinogens.

In most cases, the listed carcinogens are not distinguished from other designated substances. For example, asbestos is classified by DOT together with inflatable life rafts as an ORM-C to indicate that it is a "material ... unsuitable for shipment unless properly identified and prepared for transportation."[66] In other cases, carcinogens are listed separately, although there may not be an established policy for listing the substance. Under Clean Water Act Section 307, EPA identifies carcinogenicity as a criterion for listing the substance as a "toxic pollutant". However, there is no published set of tests or hazard levels that define carcinogenicity under Clean Water Act Section 307.

Carcinogen policy is still changing due to new data, newly suspect carcinogens, and litigation. The following list summarizes the status of regulations under each statute as they relate to hazard classification, as of January 1, 1981. These are described in more detail in the regulatory reviews for each regulation.

- RCRA: Carcinogens, mutagens, and teratogens are listed, by chemical, at 40 CFR 261.33(f) as "toxic wastes"; Appendix VIII of 40 CFR 261 includes CAG-identified carcinogens which could be the basis for listing a hazardous waste.

---

[66] 49 CFR 173.500(b)(3). Inflatable life rafts and asbestos are identified at 49 CFR 137.906 and 49 CFR 173.1090, respectively.

- TSCA: Carcinogens are identified and listed by chemical under Section 4, and are dealt with case-by-case under Sections 5 and 6. There are no established test protocols as of January 1, 1981.

- FIFRA: Carcinogenicity is a factor in classification and registration. Registration Guidelines, when finalized, will describe testing methods.

- CAA: Carcinogenic air pollutants have been listed separately, but policies proposed under Section 112--National Emission Standards for Hazardous Air Pollutants--would establish general criteria for listing carcinogens as hazardous air pollutants.[7] Four hazardous air pollutants have been designated because of their carcinogenic effects.

- CWA: Similar to the CAA, carcinogens are generally not listed separately or categorized as such. However, EPA has recently proposed, through EPA's Carcinogenic Assessment Group, a general method for designating carcinogens under Section 311.[8]

- SDWA: There is no separate listing or policy for suspect or confirmed carcinogens.

- MPRSA: The regulations under this Act prohibit the dumping of carcinogens, mutagens, or teratogens except as trace contaminants. They do not supply a procedure for their identification.

- HMTA: DOT tends to follow EPA's designations in this respect. Carcinogens are not listed separately but are included in the ORM-E class of hazardous materials.

---

[7] "National Emission Standards for Hazardous Air Pollutants: Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer," 44 FR 58642 (October 10, 1979).

[8] See the Proposed Amendment to Expand Selection Criteria 45 FR 4694 (July 9, 1980).

- CPSC: Regulations under FHSA, CPSA, and PPPA do not describe or define carcinogenicity.

- OSHA: In OSHA's proposed labeling regulations (later withdrawn), a "carcinogen" is a substance which meets the definition of "Potential Occupational Carcinogen" (20 CFR 1990.103 and 1990.143-144) or which is identified in a previous OSHA regulation as a carcinogen (20 CFR 1910).[69]

- FDA: Through the Delaney clause of the FDCA, all food and ingested color additives that are known to "cause cancer in man or animals" are prohibited in any concentration. These are dealt with case-by-case, using the "judgement of appropriately qualified scientists".[70]

As seen in the above summary, only three regulatory strategies have emerged that attempt to classify or set up a screening process for carcinogens. These are: 1) CAA, Section 112, proposed policies for regulating airborne substances posing a risk of cancer; 2) CWA, Section 311, proposed designation of hazardous substances for their carcinogenic effects on man; and 3) the proposed OSHA Cancer Policy.

All three proposed cancer policies entail a two-step process:

1) An assessment of the probability of carcinogenicity based on human epidemiological data, animal test data, and chemical structure information; and

2) An evaluation of the probability and extent of exposure to the potential carcinogen.

The first step is the most important to this analysis; the latter step involves analyzing different medias, substances and industries, and cannot be compared between regulatory programs.

EPA, through the use of the erstwhile Interagency Regulatory Liason Group (IRLG) had proposed some degree of consistency between the CAA and CWA policy. For CWA Section 311, EPA's Carcinogenic Assessment Group (CAG), formerly evaluated the data and relegated the chemical to one of three categories:[71]

---

[69] OSHA Proposed Rules on Hazards Identification, 46 FR 4412 (January 16, 1981). Withdrawn February 12, 1981, 46 FR 12020.

[70] 21 CFR 70.50(a)

- Best Evidence of Human Carcinogenicity--Positive epidemiological studies and confirmatory animal tests.
- Substantial Evidence of Human Carcinogenicity--Animal bioassay tests demonstrating the induction of malignant tumors or the induction of benign tumors that are generally recognized as early stages of malignancies, in one or more species.
- Suggestive Evidence of Human Carcinogenicity--Animal bioassay tests demonstrating the induction of non-life-shortening benign tumors and also positive results in indirect tests of tumorigenic activity (e.g., mutagencity), in vitro cell transformation, and initiation-promotion skin tests in mice.

Compounds in the first two categories were to be further evaluated for discharge potential and regulation.

CAA Section 112 proposed policies prescribed a very similar methodology, using the same IRLG terms ("best", "substantial", etc.), except the categories are arranged differently:[72]

- High Probability of Human Carcinogenicity--Substances for which "best" or "substantial" evidence exists from epidemiological and/or at least one mammalian study.
- Moderate Probability of Human Carcinogenicity--Substances for which "suggestive" evidence exists from epidemiological, animal, or short term studies.
- Low Probability of Human Carcinogenicity--Substances for which only "ancillary" evidence exists, such as from structural correlations, or for which epidemiological or animal results are judged to indicate low probability.

"Best", "substantial", and "suggestive" all had the same meanings as under CWA (listed above). The term "ancillary" was also an IRLG term, not used in the CWA determination. The meaning is self-evident from the proposed CAA regulation.

---

[71] 45 FR 46097 (June 9, 1980).

[72] 44 FR 58659 (October 10, 1979).

Unlike EPA, which sets up a gradient of three categories, OSHA's cancer policy relied on two: Category I Potential Carcinogens, and Category II Potential Carcinogens. A Potential Carcinogen had first to meet the definition of a "potential occupational carcinogen" defined as:

> "any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at the site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals." (29 CFR 1990.103)

Both categories had to meet the above definition. The two (I and II) are differentiated by the certainty of the evidence involved. A Category I Potential Carcinogen must have been demonstrated in humans with other test data as confirmation.[73] Those substances that only show suggestive evidence, or are not in concordance with other test data, were to be relegated to Category II.[74]

OSHA's Category I seems to correspond to a sum of EPA's "best" and "substantial" evidence categories. Because the OSHA definition was much more specific, however, it is difficult to compare the two methods of classification.

---

[73] For a Category I Potential Carcinogen, evidence of carcinogenicity must be demonstrated in: (i) humans, or (ii) in a single mammalian species in a long-term bioassay where the results are in concordance with some other scientifically evaluated evidence of a potential carcinogenic hazard or (iii) in a single mammalian species in an adequately conducted long-term biossay, in appropriate circumstances." (29 CFR 1990.112(a)). Concordance is demonstrated by any of the following: "positive results from independant testing in the same or other species, positive results in short-term tests, or induction of tumors at injection or implantation sites." (29 CFR 1990.112(a)).

[74] A Category II Potential Carcinogens are simply substances which: (1) "meet the criteria set forth in 1990.112(a) [for a Category I Potential Carcinogen], but the evidence is found to be only 'suggestive'" or (2) "meet the criteria set forth in 1990.112(a) in a single mammalian species without evidence of concordance" (29 CFR 1990.112(b)).

Mutagenicity and teratogenicity, are not established categories. OSHA, however, had proposed special labeling for "reproductive toxins" (teratogen) defined as: "Causes fetal wastage or undergrowth, malformation, growth retardation, or functional disorders in the products of mammalian conception, or prematurity or diminished fertility in mammals."[75]

FIRE HAZARDS

The term "fire hazard" is a relative one. Virtually anything will burn when subjected to the proper catalyst. However, the danger is significant only when the conditions required to initiate combustion correspond to those normally encountered by the material. Since ignitability depends on the physical state of chemicals, liquid, solid, and gaseous fire hazards must be analyzed separately.[76] In general, regulations that prescribe special handling, conditions of use, and particularly labeling for hazardous substances will classify fire hazards. Out of the nineteen statutes reviewed, only regulations under RCRA, FIFRA, HMTA, Coast Guard (USCG), and OSHA provide flammability definitions and testing methods.

- Liquid Fire Hazards: Essentially, the sole determinant of liquid ignition is temperature. Every liquid exhibits a "flash point" above which it emits vapors sufficient to form an ignitable mixture with the air near its surface. Without exception, all liquid fire hazard categories are based on such flash points. Nevertheless, there are many important differences between the regulations.

The flash point ranges which define the classes under the various programs differ according to the temperatures normally incident to handling the respective materials (see Exhibit 22). For example, the 140°F "ignitability" criterion established under RCRA was chosen specifically to relate to " the potential sources of ignition existing at a landfill site, such as hot truck exhaust pipes and heat from neutralization reactions."[77] In defense of this unique flash point cutoff, EPA stated that "while [the Agency] believes that maintaining consistency between its definitions of hazard and those of the Department of Transportation is a desirable goal, it does not believe that such consistency should be achieved at the expense of human health and environmental protection."[78]

---

[75] 46 FR 4448 (January 16, 1981).

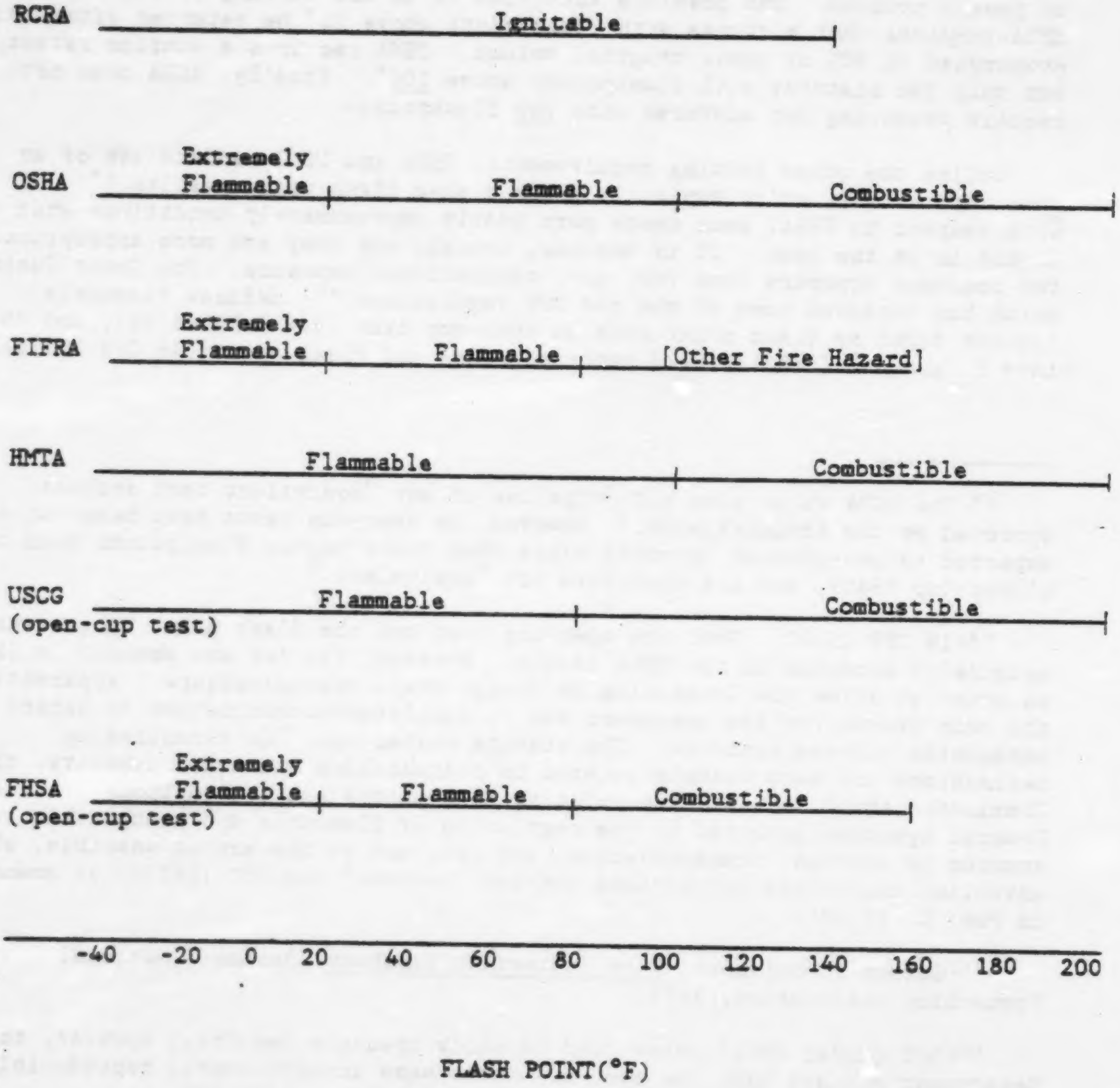
[76] Pyrophoric materials and oxidizers are discussed in the section on "Other Hazards."

[77] 42 FR 22332 (May 2, 1977).

[78] 45 FR 33108 (May 19, 1980).

EXHIBIT 22

FLASH POINT RANGES FOR LIQUID FIRE HAZARD CATEGORIES



The regulations differ not only in the flash point ranges used to define the hazard categories, but also in the test methods authorized for determining the ignition temperatures. Most of the classifications require the use of "closed-cup" tests (Pensky-Martens, Setaflash, or Tagliabue).[79] Even though there are some differences in the way that the particular tests are described and their suitability for various samples are explained, the closed-cup procedures are standard enough that the variations are not believed to pose a problem. One possible exception is in the testing of mixtures. HMTA requires that mixtures with flashpoints above 20° be retested after being evaporated to 90% of their original volume. OSHA requires a similar retest, but only for mixtures with flashpoints above 100°. Finally, RCRA does not require retesting for mixtures with *any* flashpoints.

Unlike the other testing requirements, FHSA and USCG mandate use of an *open* cup test,[80] which typically gives higher flash point results.[81] With respect to FHSA, such tests more nearly approximately conditions when the liquid is in the open. It is unclear, though, why they are more appropriate for consumer exposure than for, say, occupational exposure. The Coast Guard, which has retained some of the old DOT regulations,[82] defines flammable liquids first by flash point with an open-cup test (see Exhibit 24), and then into 5 "grades" (A-E) by Reid vapor pressure and flash point (46 CFR 30.10-22).

---

[79] The RCRA rules also authorize use of any "equivalent test methods approved by the Administrator." However, no open-cup tests have been--or are expected to be--granted approval since they yield higher flashpoints than the closed-cup tests, and are therefore not "equivalent."

[80] 16 CFR 15.43. Both the open-cup test and the flash point ranges were originally mandated in the FHSA itself. However, the Act was amended in 1978 in order to allow the Commission to change these specifications. Apparently, the main reason for the amendment was to facilitate coordination of hazard categories between agencies. The statute states that "in establishing definitions and test methods related to flammability and combustibility, the Commission shall consider the existing definitions and test methods of other Federal agencies involved in the regulation of flammable and combustible substances in storage, transportation, and use, and to the extent possible, shall establish compatible definitions and test methods" (15 USC 1261(l) as amended in Pub. L. 95-631).

[81] Gordon P. McKinnon, *Fire Protection Handbook* (Boston: National Fire Protection Association, 1976).

[82] DOT (under HMTA), also used to allow open-cup results. However, the Department decided that the open-cup tests were insufficiently reproducible to be used as a basis for determining hazard. See Docket HM-102.

- Solid Fire Hazards: The flammability of solids, unlike that of liquids, depends on more than just one factor. In addition to ambient temperature, other sources of solid ignition include internal energy, absorbed moisture, and "hot spots" formed through friction or retained heat. Unfortunately, it is currently impossible to measure all of these characteristics in the laboratory. As a result, no tests for thermal instability are totally adequate. However, classifications have been set up for flammable solids under RCRA, HMTA, FHSA and OSHA (FIFRA does not include such a classification).

In the absence of satisfactory test methods, all but the FHSA (and OSHA, to some extent),[83] regulations rely on a descriptive definition for flammable solids (see Exhibit 23). For instance, in the Preamble to the RCRA rule, the EPA pointed out that there were "no test methods capable of accurately identifying the small class of ignitable solids" to which the regulation was directed. Although EPA, along with DOT and other agencies, is working on developing an accurate test, "the absence of a test should not cause too much of a problem since generators of thermally unstable solids . . . are likely to be aware that their wastes exhibit this property.[84] However, industry representatives claim that the descriptive rules give them insufficient guidance. One observer has commented that "such a definition is full enough of obscure and nebulous phrases to prevent reasonable product classification indefinitely."[85]

In addition to prescribing different ignitability characteristics, the regulations under each Act also specify different conditions under which some of the same characteristics must be manifest. To be considered ignitable, for example, a solid must exhibit flammable properties at standard temperature and pressure under RCRA, or at any conditions "normally incident to transportation" under HMTA. Any material that meets the hazard criteria at a temperature, such as 90°F, which is above standard temperature but within the range of conditions "normally incident to transportation," is therefore classed as a flammable under HMTA only.

The regulations differ not only in the ignition characteristics, but also in the combustion [combustion characteristics describe the way a flammable solid burns after ignition] characteristics they designate as hazardous. At

---

[83] The OSHA labeling proposal mentions the same test as the FHSA regulations. However, even materials which fail the test might be classified as flammable under OSHA as long as they satisfy the remainder of the definition.

[84] Preamble to the RCRA regulations, 45 FR 33108 (May 19, 1980).

[85] Richard D. Hilton, "Consolidation of Hazardous Materials Regulations and Miscellaneous Proposals," Transportation Journal, Volume 16, Number 3 (Spring 1977).

EXHIBIT 23

DEFINITIONS OF SOLID FIRE HAZARDS

RCRA "ignitable waste"

A solid "capable, under standard temperature and pressure, of causing fire through friction, absorption of moisture, or spontaneous chemical changes and, when ignited, burns so vigorously and persistently that it creates a hazard" (40 CFR 261.21(a)(2)).

HMTA "flammable solid"

"Any solid material, other than one classed as an explosive, which, under conditions normally incident to transportation is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious transportation hazard. Included in this class are spontaneously combustible and water-reactive materials" (49 CFR 173.150).

FHSA "extremely flammable solid"

"A solid substance that ignites and burns at an ambient temperature of 80°F or less when subjected to friction, percussion, or electrical spark" (16 CFR 1500.3(c)(6)(iii)).

FHSA "flammable solid"

"A solid substance that, when tested [according to a certain procedure], ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis" (16 CFR 1500.3(c)(6)(iv)).

OSHA "flammable solid"

"A solid other than an explosive, that can cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or that can be readily ignited and, when it is ignited, continues to burn vigorously and persistently after removal of the source of ignition. A material is considered a flammable solid if, when it is tested [according to the FHSA method], it ignites and burns with a self-sustained flame at a rate greater than one- tenth of an inch per second along its major axis" OSHA Proposed Rules on Hazards Identification 46 FR 4412 (Jan. 16, 1981).

first reading, RCRA and HMTA appear to be consistent in this respect, since they both contain the phrase "...burns so vigorously and persistently as to create a. . . hazard." However, this criterion is a necessary condition for classification as a fire hazard under RCRA, but simply one of several sufficient condition under HMTA.[86] The OSHA draft regulations are similar to the HMTA rules in this respect. Any solid which, when ignited, "continues to burn vigorously and persistently after removal of the source of ignition" is considered flammable.[87]

- Gaseous Fire Hazards: In contrast to both solids and liquids, gases are rarely stored or transported in the same physical state as they are used. Instead, the materials are kept in a more economical condensed form and are released through either expansion (as in the case of compressed gases) or propulsion (as in aerosols). RCRA, FIFRA, HMTA, FHSA and OSHA have all established gaseous fire hazard classifications.

The susceptibility of gases to fire depends on three factors:

1) inherent flammability of the vapor;
2) conditions of containment; and
3) conditions of dispersal.

Standard procedures or definitions have been developed to test each one of these factors. However, the procedures and terminology for gaseous fire hazards have not been uniformly accepted. Compressed gas, for instance, is defined by the OSHA proposed labeling regulations, under HMTA, and under RCRA. The Coast Guard, as well, regulates the carriage of "liquified gases."[88] The only significant coordination has been between the RCRA and

---

[86] Actually, EPA originally tried to coordinate the RCRA regulations by proposing the "hazardous combustion" criterion as a sufficient condition. However, the definition was changed in response to industry comments that it "could be construed to include such non-hazardous materials as bark, wood chips, waste paper, sawdust, corrugated boxes, etc." (45 FR 33108 (May 19, 1980)). It is doubtful that these comments (and therefore the inconsistencies) were truly justified--scrap paper, sawdust, and woodshavings are regulated as Other Regulated Materials-C, rather than as flammable solids, under HMTA (49 CFR 173.1070,5).

[87] 46 FR 4112 (January 16, 1981).

[88] USCG regulates vessels carrying "bulk liquified gases", including some that are flammable. In this case, the Coast Guard defines a "liquefied gas" as a cargo having a vapor pressure of 25 psi at 100°F. Notice that this category is physically somewhere between the two sufficient conditions under OSHA.

HMTA definitions of "flammable (or ignitable) compressed gas", and between OSHA and FHSA definitions of "flammable gases and aerosols". Conformity was facilitated in the first case by EPA's realization that "the major hazard to the environment arising from flammable gases would be during transport."[89]

On the other hand, the types of containers and methods of storage confuse the categories: "ignitable compressed gases", "flammable aerosols",[90] and "flammable contents of self-pressurized containers" all contain compressed gases.

CORROSIVE HAZARDS

The term "corrosion" is frequently used to encompass two distinct phenomena:

1) destruction of living tissue; and
2) degradation of metal containers and transport vehicles.

Because of the differences between these two processes, it is important that they be considered separately. Although corrosive substances are regulated under almost all of the statutes in Exhibit 1, only regulations under RCRA, HMTA, FHSA, and OSHA have established specific, testable categories.

- Tissue Corrosion: Materials which corrode living tissue present a direct threat to humans and require special care in handling. They can be readily identified though a rabbit skin test. Indeed, this technique has been adopted under most regulatory authorities as the sole determinant of skin corrosivity (Exhibit 24). Even chemicals which do not meet the rabbit skin corrosion criterion may be considered corrosive if, under RCRA, HMTA, and OSHA, they are otherwise known to cause "visible destruction of or irreversible alterations in living tissue by chemical action at the site of contact."[91] FIFRA labeling regulations, however, do not specify tests, but do assign those pesticides that are: 1) "corrosive" to the skin, or 2) "corrosive; corneal opacity not reversible within 7 days" to the eye, to Toxicity Category I (most hazardous).[92]

---

[89] 43 FR 58951 (December 18, 1978).

[90] Some chloroflurocarbon propellants are also regulated by FDA, CPSC and EPA because of their effect on the ozone layer and public health.

[91] See RCRA Draft Proposal for 40 CFR 780.2 (July 29, 1980); HMTA regulations at 49 CFR 173.240; and FHSA regulations at 16 CFR 1500.3(c)(3).

[92] 40 CFR 162.10(h)91)

EXHIBIT 24

CORROSIVITY TESTS

	Tissue Corrosion		Metal Corrosion	
	Rabbit Skin Test	pH Test	Steel Test	Aluminum Test
RCRA		X	X	
HMTA	X		X	X**/
FHSA	X*/			
OSHA	X			

---

*/The period of exposure required by CPSC under FHSA is 24 hours, compared to just 4 hours required by regulations under HMTA and OSHA.

**/Chemicals which corrode aluminum are classified as ORM-B under HMTA.

The RCRA regulations, however, employ a much simpler pH criterion for corrosivity. The rabbit test was rejected in this case because of a belief that "requiring the regulated community to conduct skin corrosion tests, which necessitate the maintenance of special facilities and skilled personnel, would prove unnecessarily burdensome and would yield little in the way of extra results. The pH test was chosen as a substitute because, even in light of a CPSC survey which casts doubt on the ability of pH to predict tissue damage," EPA decided that "there is sufficient correlation between [the two] to justify the use of pH in a regulatory context, especially in view of the fact that [the Agency] is using pH as a multi-purpose measure of many elements of concern." Besides harm to human tissue, the other concerns signaled by pH include the ability of wastes

1) to promote the migration of toxic components from other wastes;

2) to react dangerously with other wastes; and

3) to harm aquatic life.[93]

- Metal corrosion: Unlike tissue corrosion, metal corrosion presents only an indirect threat to people -- either through liberation of hazardous chemicals in the same or nearby containers, or through damage to transport vehicles. Perhaps because of this indirect course of action, only two regulatory programs currently designate metal corrosion as a hazardous property. Because it deals with consumer items FHSA expressly forbids inclusion of metal corrosion, stating that "the term 'corrosion' . . . shall not refer to action on inanimate surfaces."[94]

The two regulations which do cover metal corrosion require identical steel corrosion tests (see Exhibit 27). The RCRA test was taken directly from DOT Hazardous Materials rules after EPA determined that the Agency's "concern about container damage is identical to that of DOT's in this case."[95] DOT also requires an aluminum corrosion test to identify Other Regulated Materials - B (ORM-B's), defined as those materials "capable of causing significant damage to a transport vehicle or vessel from leakage during transport."[96] The ORM-B category was created primarily for the air transport of corrosive materials, where the corrosion of aluminum could be a major safety hazard.

---

[93] 45 FR 33109 (May 19, 1980).

[94] 15 USC 1251(i).

[95] 43 FR 58951 (December 18, 1978).

[96] 49 CFR 173.500(b)(2).

REACTIVE HAZARDS

A reactive material is defined under OSHA as "a chemical substance or mixture that is able to undergo a violent, self accelerating, exothermic chemical reaction with common materials or by itself and includes a substance or mixture that falls within [one of three categories which are discussed below: organic peroxides, pressure-generating materials, and water-reactive materials]."[97] EPA found, in formulating the RCRA Regulations, that the methods currently available for testing this class of properties suffer from a number of shortcomings:[98]

> "First, these tests are too restrictive in scope and confine themselves to measuring how one specific aspect of reactivity correlates with a specific initiating condition or stress. No test is sufficiently general to even begin to measure the variety of different stresses and reactions found within the reactive classification.
>
> Second, because the reactivity of a . . . sample is a function not just of its intensive properties such as density and composition but also of its extensive properties such as mass and surface area, the reactivity of the sample as measured by the tests will not necessarily reflect the reactivity of the whole . . . .
>
> Third, most of the available tests are not of the "pass-fail" type and require subjective interpretation of results."

The unavailability of suitable test methods has forced the regulatory agencies to rely on descriptive definitions, as in the case of solid fire hazards. Because of the differences between the various types of reactivity discussed below, for the most part each type is specifically mentioned in the regulations.

Under RCRA, however, substances which would be classified separately under other statutes as explosive, water-reactive, etc., are all grouped together in the "reactive" definition. Part 261.23 of the RCRA rules give eight "properties" that parallel the subcategories established under OSHA, HMTA, and FHSA. The subcategories established under reactive hazards are discussed below. The reactive hazard definitions are shown in Exhibit 28.

---

[97] OSHA Proposed Rules on Hazards Identification 46 FR 4412 (January 16, 1981).

[98] Preamble to RCRA Regulations 45 FR 33110 (May 19, 1980).

- Explosive Hazards: The descriptions used to designate explosive hazards vary significantly from regulation to regulation. Under OSHA and RCRA, explosives are defined according to their properties, as shown in Exhibit 25. Under HMTA, however, explosives are designated according to use. Substances which produce an "instantaneous release of gas and heat," but which have a "primary or common purpose [other than] to function by explosion" are not considered explosive materials.[99] The RCRA regulations, finally, adopt an intermediate approach. They designate as "reactive" wastes which either meet the DOT criteria for "forbidden", "class A", or "class B" explosives, or are capable of detonating under any of the following conditions:[100]

1) exposure to standard temperature and pressure;
2) heating, while under confinement;
3) mixing with water; or
4) initiation from "strong" sources.

- Water-reactive Hazards: Water reactivity is designated as a separate hazard category only under OSHA. The group is defined to include any "chemical substance or mixture that reacts with water to release heat or a gas which is hazardous."[101]

However, the same water-reactive hazards are covered, at least to some extent, by other programs. The RCRA regulations, for example, classify as "reactive" any waste which "reacts violently with water, or forms potentially explosive mixtures with water".[102] Materials which, when mixed with water, "generate toxic gases, vapors, or fumes" are also covered, but only as long as they do so "in a quantity sufficient to present a danger to human health or the environment."[103] In this way, substances which are designated water-reactive under OSHA simply because they emit trace amounts of hazardous gases are excluded under RCRA.

An even greater proportion of water-reactive chemicals are excluded under HMTA. The regulations classify water-reactive solids as flammable

---

[99] 49 CFR 173.50.

[100] 40 CFR 261.23(a). See 45 FR 33122 (May 19, 1980).

[101] OSHA Proposed Rules on Hazards Identification 46 FR 4412 (January 16, 1981).

[102] 40 CFR 261.23(a)(2).

[103] 40 CFR 261.23(a)(4).

EXHIBIT 25

DEFINITIONS OF REACTIVE HAZARDS

RCRA "Reactivity"

A representative sample of the waste has any of the following properties:

(1) It is normally unstable and readily undergoes violent change without detonating.
(2) It reacts violently with water.
(3) It forms potentially explosive mixtures with water.
(4) When mixed with water, it generates toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.
(5) It is a cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.
(6) It is capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement.
(7) It is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure.
(8) It is a forbidden explosive as defined in 49 CFR 173.51, or a Class A explosive as defined in 49 CFR 173.53 or a Class B explosive as defined in 49 CFR 173.88."

HMTA "Explosive"

"Any chemical compound, mixture, or device, the primary or common purpose of which is to function by explosion, i.e., with subtantially instananeous release of gas and heat" (49 CFR 173.50).

- "Forbidden explosives" - spontaneously explosive
- "Class A explosives" - "detonating or otherwise of maximum hazard"
- "Class B explosives" - explosives which "function by rapid combustion rather than detonation" (e.g., flash powder and pyrotechnic signals)
- "Class C explosives" - "manufactured articles which contain class A, or class B, explosives, or both, as components but in restricted quantities" (e.g., small arms ammunition and certain fireworks)

EXHIBIT 25 (continued)

DEFINITIONS OF REACTIVE HAZARDS

OSHA "Reactive material"

"A substance or mixture that is able to undergo a violent, self-accelerating exothermic chemical reaction with common materials or by itself and includes a substance or mixture that falls within any of the following categories:

(i) 'Organic Peroxide' . . .
(ii) 'Pressure-generating material' . . .
(iii) 'Water-reactive material' . . ." (46 FR 4412, January 16, 1981)

materials[184], and "water-reactive pesticides" not covered elsewhere as ORM-C's.[185] However, water-reactive liquids other than pesticides are apparently not considered hazardous. In fact, even the liquid pesticides and solids may not be included, since the term "water-reactive" is never explained under HMTA other than to be loosely associated with fire hazards. FHSA regulations, finally, fail to mention water-reactive hazards at all.

- Pressure Generating Hazards: Substances which "generate pressure through decomposition, heat, or other means" were first regulated by CPSC.[186] Under FHSA, any material falls into this category

> "(A) If it explodes when subjected to an electrical spark, percussion, or the flame of a burning paraffin candle for 5 seconds or less.
>
> (B) If it expels the closure of its container, or bursts its container, when held at or below 130°F for 2 days or less.
>
> (C) If it erupts from its opened container at a temperature of 130°F or less after having been held in the closed container at 130°F for 2 days.
>
> (D) If it comprises the contents of a self-pressurized container."[187]

Presumably as a result of inadequacies in the test procedures, other regulations have adopted descriptive definitions for pressure-generating hazards. For example, under OSHA, the hazard class is defined to include any substance or mixture that "must be protected from spontaneous polymerization by the addition of an inhibitor, or by refrigeration or other thermal control; or may decompose to release gas in its container."[188]

RCRA regulations do not establish separate categories for pressure-generating materials. However they do cover these substances. RCRA classifies as "reactive" any waste which is "normally unstable and readily undergoes violent change without detonating."[109] Included in this definition are chemicals that exhibit a "tendency to autopolymerize."[110]

---

[184] 49 CFR 173.150.

[185] 49 CFR 173.1040.

[186] 15 USC 1261 (f)(1)(A)(vi).

[187] 16 CFR 1500.3(c)(7)(i)(A-D).

[188] 46 FR 4447 (January 16, 1981).

- Pyrophoric materials: Under OSHA, a "pyrophoric material" is defined as "a chemical substance or mixture that ignites spontaneously in dry or moist air at or below 130°F (54.4°C)."[111] The same definition is employed in the HMTA regulations, but only as applied to pyrophoric liquids.[112] Solids which are "spontaneously combustible" are classified as DOT flammables.[113]

The same types of materials may also be covered under RCRA. Any substance that "is normally unstable and readily undergoes violent change without detonating" is included as "reactive" in the regulations.[114] The Notice of Proposed Rulemaking (NPR) made it clear that "reactivity includes the tendency to . . . create a vigorous reaction with air."[115] In addition solids "capable, under standard tempature and pressure, of causing fire through . . . spontaneous chemical changes" are classified as "ignitable."[116]

- Oxidizers: An oxidizer is defined under RCRA,[117] and HMTA as "a substance . . . that yields oxygen readily to stimulate the combustion of organic matter."[118] The proposed OSHA definition is only slightly different, meaning "a substance or mixture that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases."[119]

---

[109] 40 CFR 261.23(a)(1).

[110] 43 FR 58952 (December 18, 1978).

[111] 46 FR 4447 (January 16, 1981).

[112] 49 CFR 173.115(c).

[113] 49 CFR 173.150.

[114] 40 CFR 261.23(a)(1).

[115] 43 FR 58952 (December 18, 1978).

[116] 40 CFR 261.21(a)(2).

[117] 40 CFR 261.21(a)(4); Oxidizers are classified as "ignitable" materials under RCRA, using the DOT definition.

[118] 49 CFR 173.151.

[119] 46 FR 4447 (January 16, 1981).

- Organic peroxides: Besides cyanide and sulfide compounds, the organic peroxide category is the only one which is based on the structure, rather than on the properties, of chemicals. The group is defined under HMTA and OSHA to include any "organic compound that contains the bivalent -0-0- structure and which may be considered a structural derivative of hydrogen peroxide, in which one or both of the hydrogen atoms has been replaced by an organic radical."[120] FHSA and RCRA regulations do not specifically mention organic peroxides; however, they do include these substances if they exhibit other reactive characteristics such as explosivity.

- Cyanide and Sulfide Compounds: Cyanide and sulfide compounds are specifically targeted for regulation only under RCRA. The rules designate as "reactive" any "cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment."[121] The particular pH conditions were chosen because they "are likely to be the most stringent encountered by cyanide and sulfide bearing wastes."[122]

RADIOACTIVE HAZARDS

Radiation designation and/or protection regulations of some kind have been issued by all of the agencies discussed in this review: EPA, DOT, NRC, CPSC, FDA, and USDA, along with other executive departments, like Defense and Energy. As well, other government bodies have duties that require dealing with radiation. This abundance of agencies involved in radiation protection has evolved from the increasing use of radioactivity and the increasing sources of exposure. Possible sources of radiation exposure include:

- occupationally-related radiation
- water contamination
- radioactive emissions into the air
- consumer exposure through electronic and other products
- naturally occurring radioactivity through mining and other activities.

---

[120] 49 CFR 173.151a; OSHA Proposed Rules on Hazard Identification 46 FR 4447 (January 16, 1981).

[121] 40 CFR 261.23(a)(5).

[122] 45 FR 33110 (May 19, 1980).

Because of the diversity of sources and types of radiation, there is no one definition for "radiation" or radioactive substance. Instead, radioactivity is defined in terms of the type of substance or activity that is regulated under each particular statute. The next paragraphs discuss how each agency defines radioactive hazards.

Under the AEA, NRC regulations define "radiation" as "any or all of the following: alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electronics, high-speed protons, and other atomic particles; but not sound or radio waves, or visible, infrared, or ultraviolet light".[123] However, the AEA gives the authority to regulate only "the processing and utilization of *source*, *byproduct*, and *special* nuclear material".[124] These are defined as:

- **Source material**: (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of: (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material (10 CFR 40.3).
- **By-product material**: any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material (10 CFR 30.4(d)).[125]
- **Special nuclear material**: (1) plutonium, uranium 233, uranium enriched in the isotype 233 or in the isotope 235, and any other material which the Commission . . . determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material (10 CFR Section 70.4(M)).

---

[123] 10 CFR 20.3.

[124] 42 U.S.C. 2012 (emphasis added).

[125] By product material is also defined in 10 CFR 40.4(a), for use in Part 40, which deals with mining and processing of ores, as "the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed, primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute "by-product" material within this definition."

Note that only the first definition, of "radiation", really defines a class of radioactive materials -- the other three (source, byproduct, and special nuclear material) merely define the kinds of radioactive materials covered under AEA.

The NRC definitions form the basis for regulations promulgated by other agencies. EPA utilizes the same definition of "radiation" and "radioactive material" in the regulations promulgated by and transferred to EPA under AEA. Also, the CAA amendments of 1977 define "radioactive pollutant" (Section 122(a)) as "source material, special nuclear material, and byproduct material" (42 U.S.C. 7422), and uses the same definitions as NRC for the three materials.

Radioactive substances are also regulated by EPA under SDWA and MPRSA, however neither provide an explicit definition of "radioactivity" or radioactive substances." Drinking Water Regulations prescribe maximum contaminant levels for several specific isotopes or types of radiation (radium, alpha, beta particles, and protons), and also set a maximum dose equivalent for others.[126/] This is a listing procedure only, and does not classify materials as radioactive: MPRSA, in the Act itself, prohibits the dumping of "High-level radioactive waste", which is defined in terms of its source rather than a particular radioactivity level.[127/] All other radioactive wastes are not defined as "low-level", but are also under special restrictions (40 CFR 227.11).

Radioactive substances may soon be regulated under RCRA. EPA has already proposed "to list the following radioactive materials as hazardous wastes: waste rock and overburden from uranium mining; overburden and slimes from phosphate surface mining; waste gypsum from phosphoric acid production; and slag and fluid bed prills from elemental phosphorus production." Development of final rules, however, was postponed pending Congressional action on H.R. 3994, (passed as S. 1156 in October, 1981), a reauthorization bill which temporarily suspended EPA's authority to control energy-related radioactive wastes except as necessary "to prevent radiation exposure which presents an unreasonable risk to human health from the use in construction or land reclamation (with or without revegetation) of solid waste from the extraction,

---

[126/] 40 CFR 141. The maximum dose equivalents for all radionuclides are not specified, but 40 CFR 141 refers the reader to those specified in "Maximum Permissible Body Burdens and Concentration of Radionuclides in Air or Water for Occupational Exposure" NBS Handbook 69, U.S. Department of Commerce, 1963.

[127/] 40 CFR 227.30. High-level radioactive wastes means the aqueous waste resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel or irradiated fuel from nuclear power reactors.

beneficiation or processing of phosphate rock or the extraction of uranium ore."[128]

OSHA, like EPA, uses the NRC definition of "radiation". However, OSHA differs in the definition of "radioactive material". According to OSHA, (29 CFR 1910.96(a)(2)) "radioactive material means any material which emits, by spontaneous nuclear disintegration, corpuscular or electromagnetic emanations". Because OSHA's authority covers more types of radiation than NRC, which is limited to source, special nuclear and byproduct material, OSHA has set up two categories. "Ionizing radiation", (which includes the definition above); and "non-ionizing radiation," which includes sonic, ultraviolet, microwave, and other electromagnetic waves that are not emitted by means of spontaneous nuclear disintegration.

Rules promulgated under both HMTA and FHSA provide the simplest definition -- they designate as "radioactive" substances which emit ionizing radiation.[129] FHSA regulations supplement the definition given in the Act: "Radioactive substance" means a substance which, because of nuclear instability, emits electromagnetic and/or particulate radiation capable of producing ions in its passage through matter" (16 CFR 1500.3(c)(8)). The DOT regulations, unlike any other radioactive regulations, exclude materials in which "the estimated specific activity is not greater than .002 microcuries per gram of material.[130]

FDA, unlike DOT and CPSC, has a complicated system of identification for radioactivity. The reason for this is the diversity of sources FDA regulates: electronic products, microwave devices, medical uses of radioactivity, and others.[131] Part 1000.3 of 21 CFR provides definitions for the following terms: "Electronic product radiation," "electromagnetic radiation", "particulate radiation", and "infrasonic, sonic (or audible) and ultrasonic waves." The FDA definitions tend to include all types of radiation, including ionizing and nonionizing radioactivity. FDA differentiates between electromagnetic radiation and particulate radiation, while NRC and OSHA divide radiation into ionizing and non-ionizing forms. The NRC definition, used by EPA and OSHA, covers all particulate radiation, as defined by FDA, and some other types of electromagnetic radiation (e.g. X-rays, gamma rays) included under FDA.

---

[128] 45 FR 33086 (May 19, 1980).

[129] 49 CFR 173.389(e); 15 USC 1261(m). See 16 CFR 1500.3(c)(8).

[130] 49 CFR 173.389(e). This exclusion is based on the statutory language of the HMTA, §108(b), 49USC §1807(b).

[131] 21 CFR 1000.

One other problem with radiation protection is the units used to express radioactivity. The basic unit of measurement is how much radiation is emitted, expressed in terms of the curie. The dose equivalent measurement is extrapolated from the curie, and is expressed in rads or (usually) rems.[132] The dose equivalent is based on "absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiations and its spatial distribution in the body." Consequently the maximum dose equivalent may be set at different levels for different parts of the body, especially since some organs are more susceptible to damage or health effects.

The HMTA regulations express the relative radioactivity of a substance through curies only. Most agencies, including EPA, NRC, OSHA, and FDA use a combination of the two measurements for regulation. For instance, under SDWA, EPA sets a maximum contaminant level for radioactivity that would produce a dose equivalent of 4 millirems/yr. to the whole body or any organ. However, for certain radionuclides, EPA also sets maximum concentrations, rather than dose equivalents, which are expressed in curies/liter.

In summary, the regulations governing the classification of radioactive substances are diverse and overlapping. The definitions tend to outline the type of substances regulated for radiation protection under each statute. NRC, although it has limited authority, has set the primary standards for radioactive hazard classification. However, some types of radiation, especially naturally occurring and accelerator-produced radioactivity and other low-level radioactivity are not covered in the NRC classification. The Federal Regulatory Council, set up in 1960 to deal with interagency jurisdiction over radiation, may be, in the future, providing more comprehensive classifications for radiation protection.[133]

OTHER HAZARD CLASSIFICATIONS

- Irritants: Under FHSA, an irritant is defined as "a chemical substance or mixture, not a corrosive, which on immediate, prolonged, or repeated contact with normal living tissue induces a local inflammatory response."[134] The regulations do not rely exclusively on this descriptive definition, however. Instead, they also require industry to perform rabbit tests on all substances not shown by human experience to irritate skin or eyes.[135] The proposed OSHA definition is almost identical to the one under FHSA, except that it is more specific: an irritant induces an "immediate or delayed onset of an acute, subacute, or chronic local inflammatory response in the skin, eyes, or mucous membranes by chemical action". This definition also prescribes the rabbit tests described in the CPSC regulations.

---

[132] 40 CFR 192.02 defines the "curie" as: "that quantity of radioactive material producing 37 billion nuclear transformations per second. (One millicurie (mCi)=0.001 Ci.)" and "dose equivalent" as: the product of absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiation and its spatial distribution in the body. The unit of dose equivalent is the rem (one millirem (mrem)=0.001 rem.)" These definitions are standard.

[133] Bureau of National Affairs Environment Reporter, August 8, 1980, p. 554.

A special classification for irritants has also been established under HMTA, but it differs from the OSHA and FHSA categories in a number of ways:

(1) Only the HMTA rules specify that "irritating materials" must "give off . . . fumes."[136] In this way, substances with low vapor pressures that cause irritation through direct contact with living tissue are effectively excluded.

(2) The fumes generated by DOT irritants must not simply be irritating, but "intensely irritating (emphasis added)."[137] This phrase has been interpreted to mean that the material must be irritating "to the extent that [a person] cannot take the action necessary to cope with the situation in the event of leakage of the material."[138]

(3) A material may qualify as an HMTA irritant even if it only exhibits hazardous properties "upon contact with fire"[139] (as in the case of edible tallow).

Some of these differences are corrected for by DOT through designation of a second category for irritating materials. The "ORM-A" classification covers any "material which has an anesthetic, irritating, noxious, toxic, or other similar property and which can cause extreme annoyance or discomfort to passengers and crew in the even of leakage during transportation."[140]

---

[134] 15 USC 1261 (j).

[135] The rabbit tests, including patch tests on abraded and intact skin and eyes, are described at 16 CFR 1500.41.

[136] 49 CFR 173.381(a).

[137] Ibid.

[138] Bierlein, Redbook on Transportation of Hazardous Materials.

[139] 49 CFR 173.381(a).

Finally, FIFRA labeling, packaging, and classification criteria utilize skin and eye effects. They do not define "irritant" per se, but are descriptive categories that lead to special labeling, packaging, or use. There are no animal or other tests prescribed in the regulations.[141]

- Sensitizers: The FHSA defines a "strong" sensitizer" as "substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance".[142] The CPSC regulations further clarify this definition by setting up two basic types of sensitizers:

> "A 'strong allergic sensitizer' is a substance that produces an allergic sensitization in a substantial number of persons who come into contact with it. An allergic sensitization develops by means of an 'antibody mechanism' . . . An allergic reaction ordinarily does not develop on first contact because of the necessity of prior exposure to the substance in question. The sensitized tissue exhibits a greatly increased capacity to react to subsequent exposures of the offending agent."
>
> "A 'photodynamic sensitizer' is a substance that causes an alteration in the skin or mucous membranes in general or to the skin or mucous membranes at the site of contact so that when these areas are subsequently exposed to ordinary sunlight (or equivalent radiant energy) an inflammatory reaction will develop."[143]

Both types are also regulated under OSHA. The proposed OSHA definition is essentially the same as FHSA, except again it is more specific. A "sensitizer" causes "humans of either sex, normal or medically disabled" to develop a hypersensitive allergic reaction, or a photodynamic reaction. They also elaborate on the hypersensitive reaction by including "the anaphylactic, immediate, delayed, or fixed type, and may be of acute, subacute, or chronic duration."[144] The coverage is far from uniform, since the responsibility for identifying individual sensitizers rests with industry under OSHA and with CPSC under FHSA. Sensitizers may also be covered under other statutes. Unfortunately, it is unclear to what extent a sensitizer qualifies either as "a material which has an anesthetic, irritating, noxious, toxic, or other similar property and which can cause extreme annoyance or discomfort to passangers and crew in the event of leakage during transportation" (the definition of "ORM-A" under HMTA).[145]

---

[140] 49 CFR 173.500(b)(1).

[141] 40 CFR I62.10 (See FIFRA Regulatory Review, Volume 2).

[142] FHSA 15 USC 1261(k).

[143] 16 CFR 1500.3(c)(5).

- Compressed Gases: Gases which present a hazard because of their compressed state of storage, rather than because of any intrinsic property such as flammability or toxicity, are regulated only under HMTA and OSHA (49 CFR 173.300(a)). However, they may be included under other statutes, but in different classes. "Compressed gases" may be flammable gases, pressure generating, reactive, or pose other hazards. The regulations employ three basic criteria to identify hazardous compressed gases:

  1) absolute pressure in the container greater than 40 psi at 70°F;

  2) absolute pressure in the container greater than 140 psi at 130°F; and

  3) vapor pressure of any flammable liquid in the container greater than 40 psia at 100°F.

The only inconsistency is the absence of the final criterion for OSHA.

The "compressed gas" classification overlaps considerably with other categories including pressure-generating substances and flammable gases. One particular inconsistency is the placement of "self-pressurized containers". Under CPSC, they are regulated as a substance which "generates pressure through decomposition, heat or other means". FIFRA regulations supply special labeling for flammable or explosive pesticides in "pressurized containers" but do not supply a definition of such.

- Etiologic Agents: Etiologic agents are currently regulated by EPA, DOT, USDA, and FDA. The category is defined by DOT to include any "viable microorganism, or its toxin, which causes or may cause human disease, and is limited to those agents listed in 42 CFR 72.25(c) of the regulations of the Department of Health [and Human Services]."[146]

---

[144] 46 FR 4448 (January 16, 1981) (Proposed Rule).

[145] 49 CFR 173.500(b)(1).

[146] 49 CFR 173.386(a)(1).

Besides the Public Health Service regulations mentioned in the DOT definition of etiological agents above, infectious agents are also regulated by FDA and USDA through their inspection of food sold in or affected by interstate commerce. None of these regulations, however, provide for a classification of etiological agents.

EPA may regulate infectious agents through the CWA, MPRSA, SDWA, and RCRA. The water quality standards and effluent guidelines under CWA use fecal coliform bacteria as an indicator of sanitary water quality. The water quality standards are also used for permitting under MPRSA. The SDWA provides the enforcement authority for the Public Health Service fecal coliform levels for drinking water. Both SDWA and CWA regulations, however, only deal with a limited kind of etiological agent and do not provide a particular classification. Etiological agents are used as indicators of water quality only.

The same types of substances may also soon be regulated by EPA under RCRA. The agency has already proposed listing (as hazardous wastes) "infectious wastes generated by certain departments in health care facilities and veterinary hospitals, by laboratories handling etiologic agents, and by sewage treatment facilities, unless the wastes were sterilized or incinerated." The agency has published a list of infectious agents proposed to make solid waste hazardous. The final rule, however, has been delayed until treatment standards for the wastes can be developed.[147]

---

[147] 45 FR 33087 (May 19, 1980).

V. APPENDIX A

SCHEMATIC DIAGRAMS OF KEY LAWS

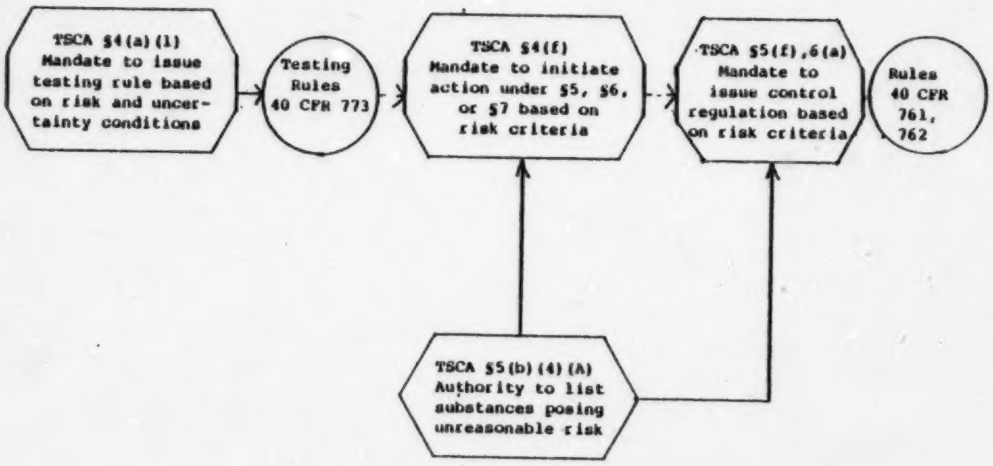
- Toxic Substances Control Act (TSCA)
- Clean Water Act (CWA)
- Safe Drinking Water Act (SDWA)
- Marine Protection, Research, and Sanctuaries Act (MPRSA)
- Resource Conservation and Recovery Act (RCRA)
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Clean Air Act (CAA)
- Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)
- Occupational Safety and Health Act (OSHA)
- Hazardous Materials Transportation Act
- Bulk Flammable and Combustible Liquids Act (BFCLA)
- Dangerous Cargo Act (DCA)
- Port and Waterway Safety Act (PWSA)
- Food, Drug, and Cosmetic Act (FDCA)
- Consumer Product Safety Act (CPSA)
- Federal Hazardous Substances Act (FHSA)
- Flammable Fabrics Act (FFA)
- Atomic Energy Act (AEA)

As a means of further illustrating the different structures of the chemical control laws, ICF have developed schematic diagrams of the key authorities. The different geometric symbols used are coded as follows:

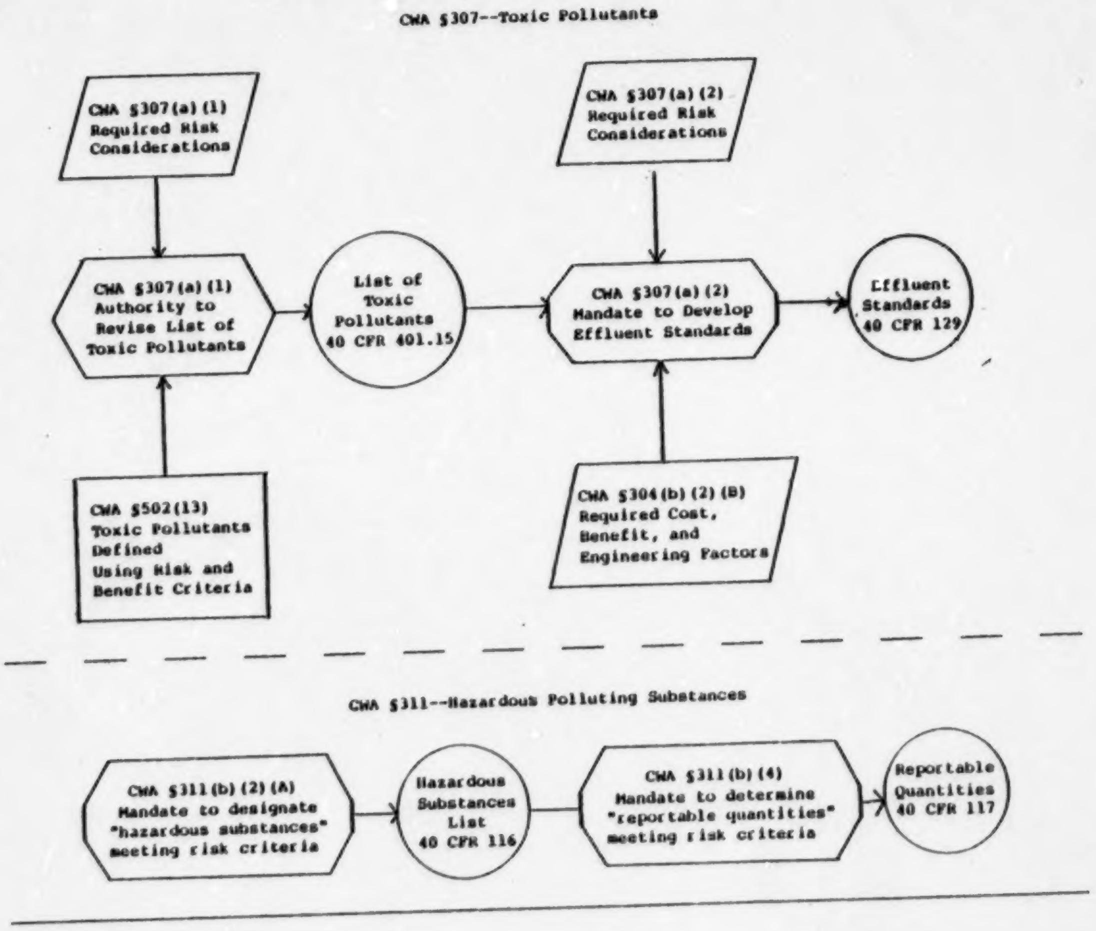
"hexagon" = statutory authority to designate or regulate
"octagon" = statutory mandate to designate or regulate
"rectangle" = statutory definition(s)
"parallelogram" = required considerations
"circle" = agency rules or standards

SCHEMATIC OF TOXIC SUBSTANCES CONTROL ACT (TSCA) DESIGNATION AUTHORITY

TSCA §4, §5, §6

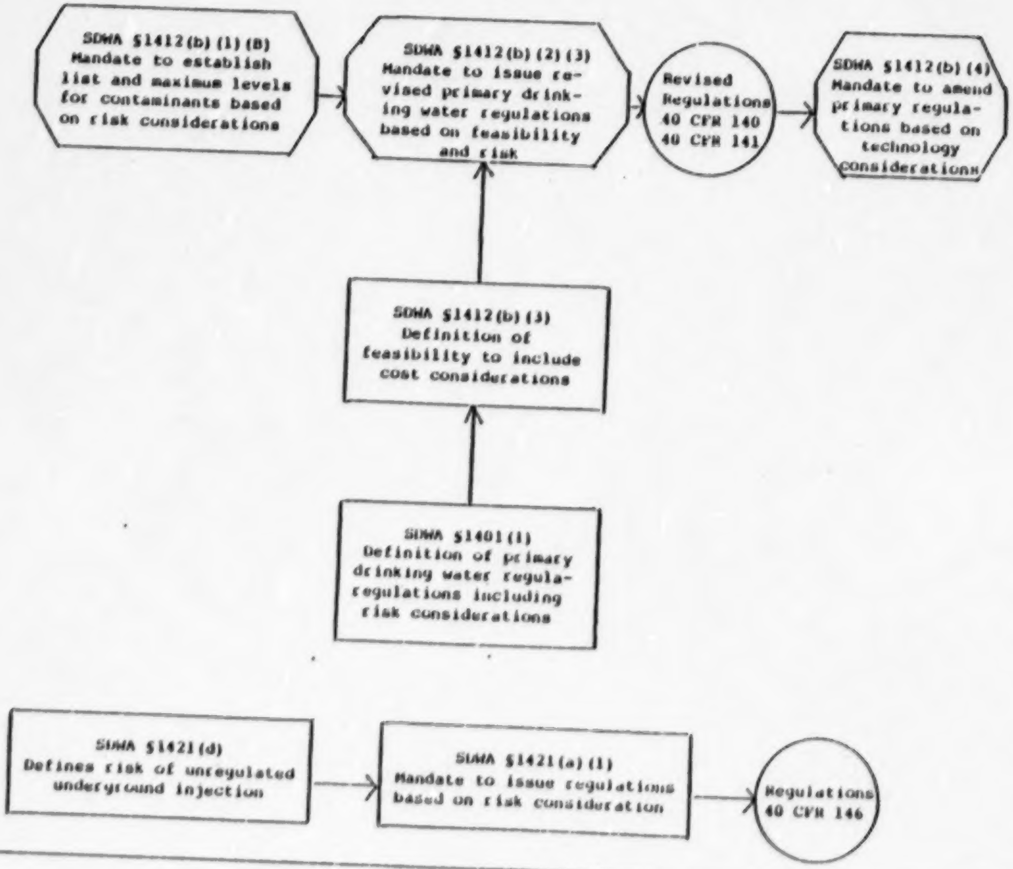

TSCA §4(a)(1) Mandate to issue testing rule based on risk and uncertainty conditions
Testing Rules 40 CFR 773
TSCA §4(f) Mandate to initiate action under §5, §6, or §7 based on risk criteria
TSCA §5(f),6(a) Mandate to issue control regulation based on risk criteria
Rules 40 CFR 761, 762
TSCA §5(b)(4)(A) Authority to list substances posing unreasonable risk

SCHEMATIC OF CLEAN WATER ACT (CWA) DESIGNATION AUTHORITY


CWA §307--Toxic Pollutants
CWA §307(a)(1) Required Risk Considerations
CWA §307(a)(2) Required Risk Considerations
CWA §307(a)(1) Authority to Revise List of Toxic Pollutants
List of Toxic Pollutants 40 CFR 401.15
CWA §307(a)(2) Mandate to Develop Effluent Standards
Effluent Standards 40 CFR 129
CWA §502(13) Toxic Pollutants Defined Using Risk and Benefit Criteria
CWA §304(b)(2)(B) Required Cost, Benefit, and Engineering Factors
CWA §311--Hazardous Polluting Substances
CWA §311(b)(2)(A) Mandate to designate "hazardous substances" meeting risk criteria
Hazardous Substances List 40 CFR 116
CWA §311(b)(4) Mandate to determine "reportable quantities" meeting risk criteria
Reportable Quantities 40 CFR 117
]

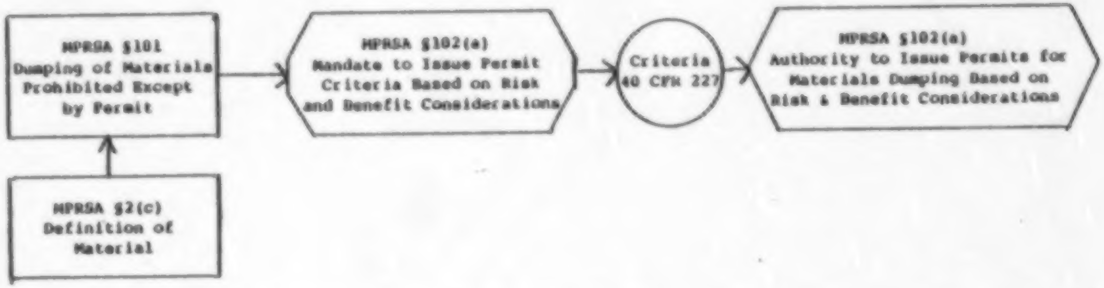
SCHEMATIC OF SAFE DRINKING WATER ACT (SDWA) DESIGNATION AUTHORITY

SDWA §1412, §1401, §1421


SDWA §1412(b)(1)(B)
Mandate to establish list and maximum levels for contaminants based on risk considerations
SDWA §1412(b)(2)(3)
Mandate to issue revised primary drinking water regulations based on feasibility and risk
Revised Regulations 40 CFR 140 40 CFR 141
SDWA §1412(b)(4)
Mandate to amend primary regulations based on technology considerations
SDWA §1412(b)(3)
Definition of feasibility to include cost considerations
SDWA §1401(1)
Definition of primary drinking water regula-regulations including risk considerations
SDWA §1421(d)
Defines risk of unregulated underground injection
SDWA §1421(a)(1)
Mandate to issue regulations based on risk consideration
Regulations 40 CFR 146

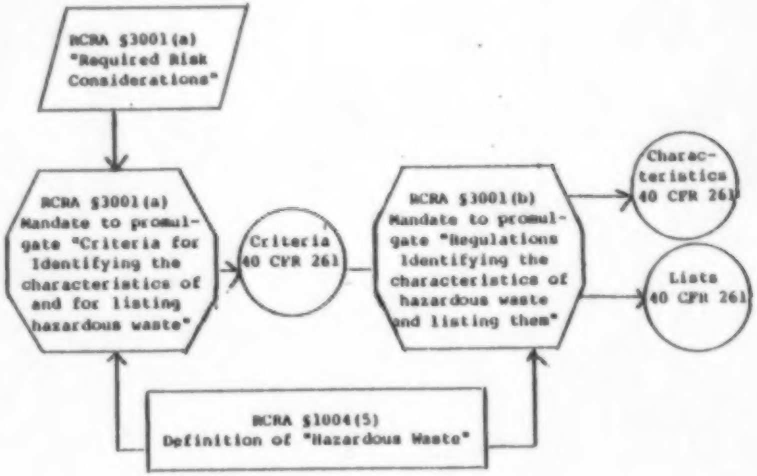
SCHEMATIC OF MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT (MPRSA) DESIGNATION AUTHORITY

MPRSA §101, §102, §2


MPRSA §101
Dumping of Materials Prohibited Except by Permit
MPRSA §2(c)
Definition of Material
MPRSA §102(a)
Mandate to Issue Permit Criteria Based on Risk and Benefit Considerations
Criteria
40 CFR 227
MPRSA §102(a)
Authority to Issue Permits for Materials Dumping Based on Risk & Benefit Considerations

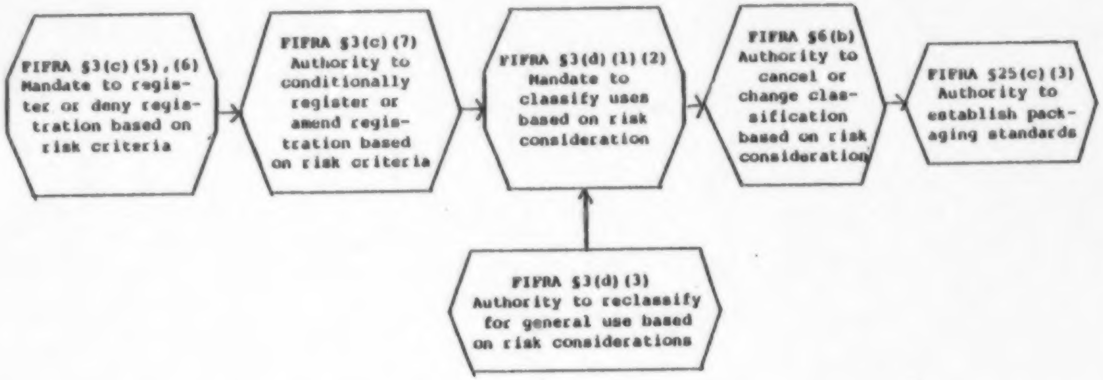
SCHEMATIC OF RESOURCE CONSERVATION AND RECOVERY ACT (RCRA) DESIGNATION AUTHORITY

RCRA §3001, 3002, 1004


RCRA §3001(a)
"Required Risk Considerations"
RCRA §3001(a)
Mandate to promulgate "Criteria for Identifying the characteristics of and for listing hazardous waste"
Criteria
40 CFR 261
RCRA §3001(b)
Mandate to promulgate "Regulations Identifying the characteristics of hazardous waste and listing them"
Characteristics
40 CFR 261
Lists
40 CFR 261
RCRA §1004(5)
Definition of "Hazardous Waste"

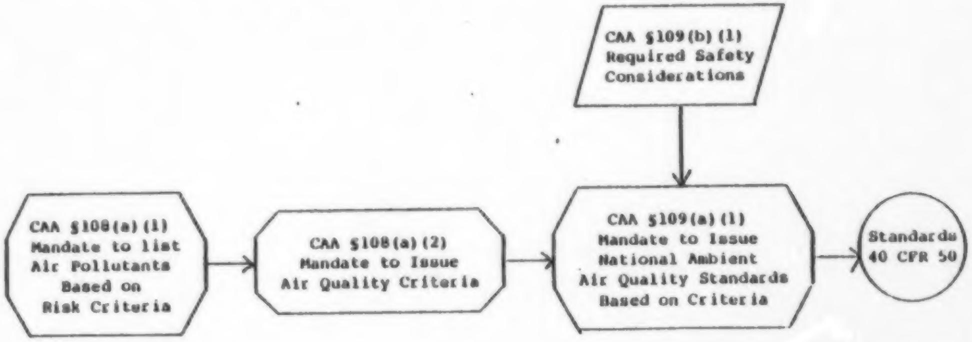
- SCHEMATIC OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) DESIGNATION AUTHORITY

FIFRA §3, §6, §25

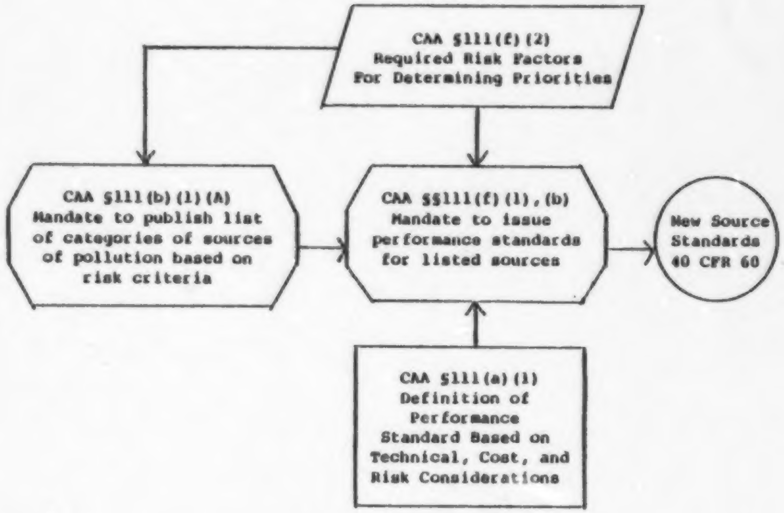

FIFRA §3(c)(5),(6) Mandate to register or deny registration based on risk criteria
FIFRA §3(c)(7) Authority to conditionally register or amend registration based on risk criteria
FIFRA §3(d)(1)(2) Mandate to classify uses based on risk consideration
FIFRA §6(b) Authority to cancel or change classification based on risk consideration
FIFRA §25(c)(3) Authority to establish packaging standards
FIFRA §3(d)(3) Authority to reclassify for general use based on risk considerations

SCHEMATIC OF CLEAN AIR ACT (CAA) DESIGNATION AUTHORITY

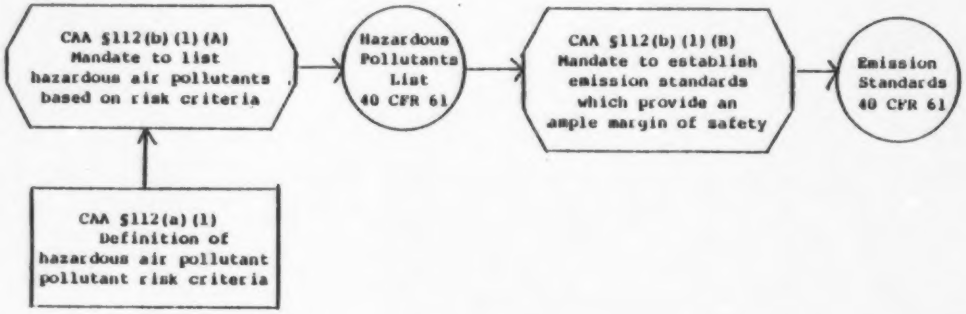
CAA §108, 109--National Ambient Air Quality Standards (NAAQS)


CAA §109(b)(1) Required Safety Considerations
CAA §108(a)(1) Mandate to list Air Pollutants Based on Risk Criteria
CAA §108(a)(2) Mandate to Issue Air Quality Criteria
CAA §109(a)(1) Mandate to Issue National Ambient Air Quality Standards Based on Criteria
Standards 40 CFR 50

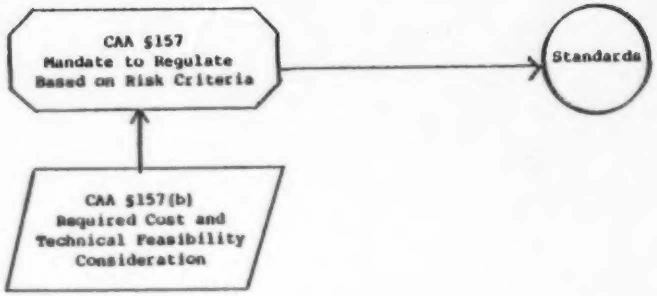
CAA §111--New Source Performance Standards (NSPS)


CAA §111(f)(2)
Required Risk Factors
For Determining Priorities
CAA §111(b)(1)(A)
Mandate to publish list
of categories of sources
of pollution based on
risk criteria
CAA §§111(f)(1),(b)
Mandate to issue
performance standards
for listed sources
New Source
Standards
40 CFR 60
CAA §111(a)(1)
Definition of
Performance
Standard Based on
Technical, Cost, and
Risk Considerations

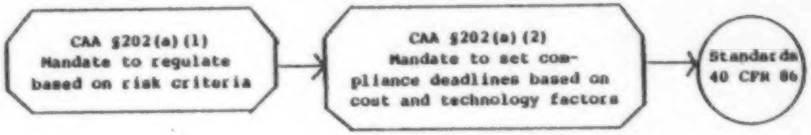
CAA §112--National Emission Standards for Hazardous Air Pollutants (NESHAPs)


CAA §112(b)(1)(A)
Mandate to list
hazardous air pollutants
based on risk criteria
Hazardous
Pollutants
List
40 CFR 61
CAA §112(b)(1)(B)
Mandate to establish
emission standards
which provide an
ample margin of safety
Emission
Standards
40 CFR 61
CAA §112(a)(1)
Definition of
hazardous air pollutant
pollutant risk criteria

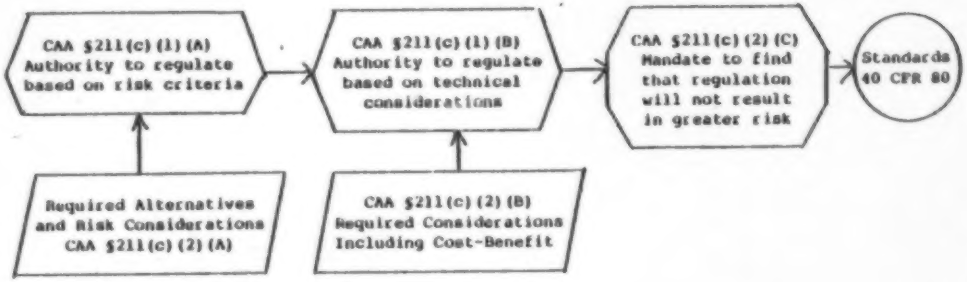
CAA §157--Ozone Protection


CAA §157
Mandate to Regulate
Based on Risk Criteria
Standards
CAA §157(b)
Required Cost and
Technical Feasibility
Consideration

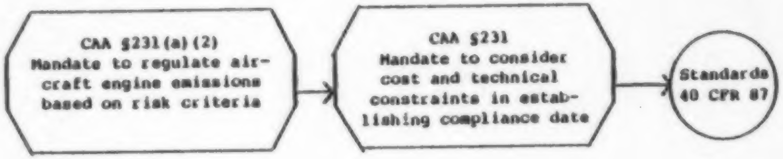
CAA §202--Motor Vehicle Emissions Standards


CAA §202(a)(1)
Mandate to regulate
based on risk criteria
CAA §202(a)(2)
Mandate to set compliance deadlines based on
cost and technology factors
Standards
40 CFR 86

CAA §211--Fuels and Additives Standards

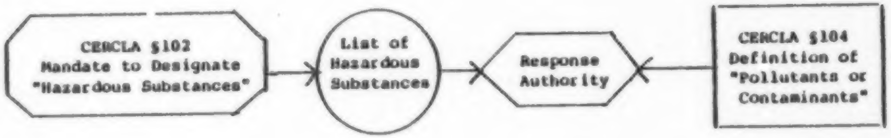

CAA §211(c)(1)(A)
Authority to regulate
based on risk criteria
CAA §211(c)(1)(B)
Authority to regulate
based on technical
considerations
CAA §211(c)(2)(C)
Mandate to find
that regulation
will not result
in greater risk
Standards
40 CFR 80
Required Alternatives
and Risk Considerations
CAA §211(c)(2)(A)
CAA §211(c)(2)(B)
Required Considerations
Including Cost-Benefit

CAA §231--Aircraft Emissions

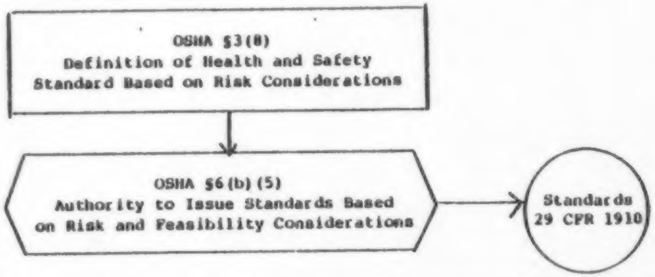

CAA §231(a)(2)
Mandate to regulate aircraft engine emissions based on risk criteria
CAA §231
Mandate to consider cost and technical constraints in establishing compliance date
Standards 40 CFR 87

SCHEMATIC OF COMPREHENSIVE ENVIRONMENTAL RESPONSE AND LIABILITY ACT (CERCLA [Superfund])
DESIGNATION AUTHORITY

CERCLA §102, §104

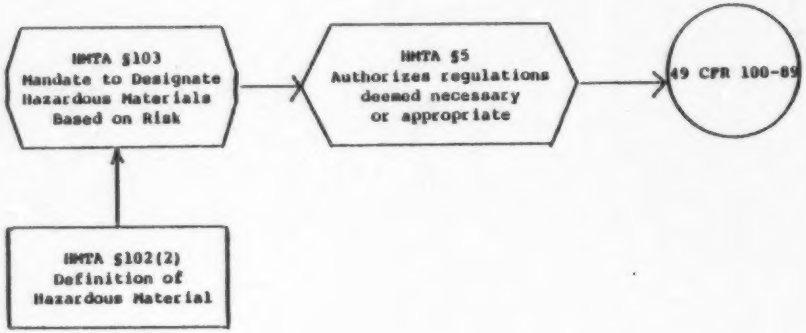

CERCLA §102
Mandate to Designate "Hazardous Substances"
List of Hazardous Substances
Response Authority
CERCLA §104
Definition of "Pollutants or Contaminants"

SCHEMATIC OF OCCUPATIONAL SAFETY AND HEALTH ACT (OSHA) DESIGNATION AUTHORITY
OSHA §3, §6

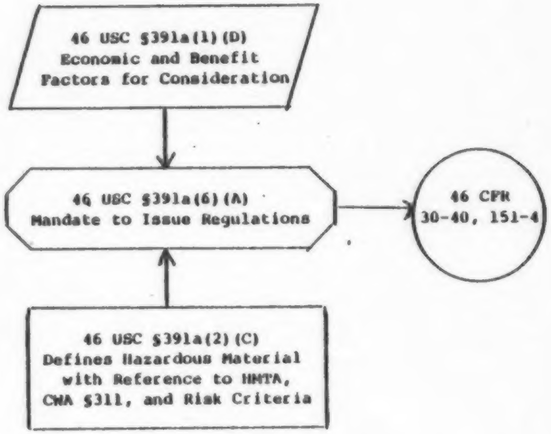

OSHA §3(8)
Definition of Health and Safety Standard Based on Risk Considerations
OSHA §6(b)(5)
Authority to Issue Standards Based on Risk and Feasibility Considerations
Standards 29 CFR 1910

SCHEMATIC OF HAZARDOUS MATERIALS TRANSPORTATION ACT (HMTA) DESIGNATION AUTHORITY

HMTA §103, §5, §102

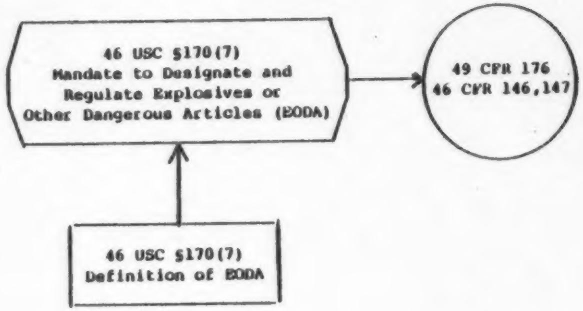

HMTA §103
Mandate to Designate
Hazardous Materials
Based on Risk
HMTA §5
Authorizes regulations
deemed necessary
or appropriate
49 CFR 100-89
HMTA §102(2)
Definition of
Hazardous Material

SCHEMATIC OF BULK FLAMMABLE AND COMBUSTIBLE LIQUIDS ACT (BFCLA) (USCG)
46 USC §391


46 USC §391a(1)(D)
Economic and Benefit
Factors for Consideration
46 USC §391a(6)(A)
Mandate to Issue Regulations
46 CFR
30-40, 151-4
46 USC §391a(2)(C)
Defines Hazardous Material
with Reference to HMTA,
CWA §311, and Risk Criteria

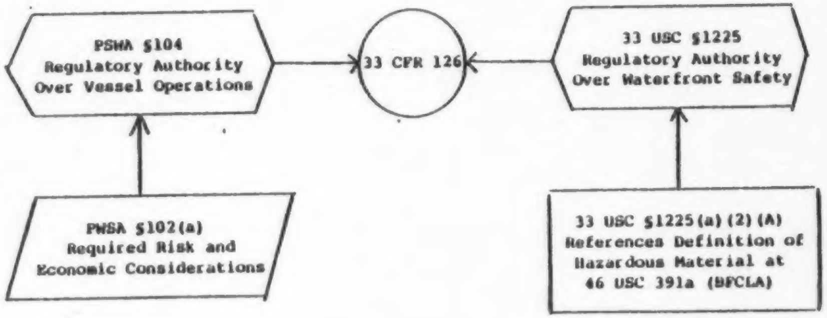
SCHEMATIC OF DANGEROUS CARGO ACT (DCA) DESIGNATION AUTHORITY

46 USC §170


46 USC §170(7)
Mandate to Designate and
Regulate Explosives or
Other Dangerous Articles (EODA)
49 CFR 176
46 CFR 146,147
46 USC §170(7)
Definition of EODA

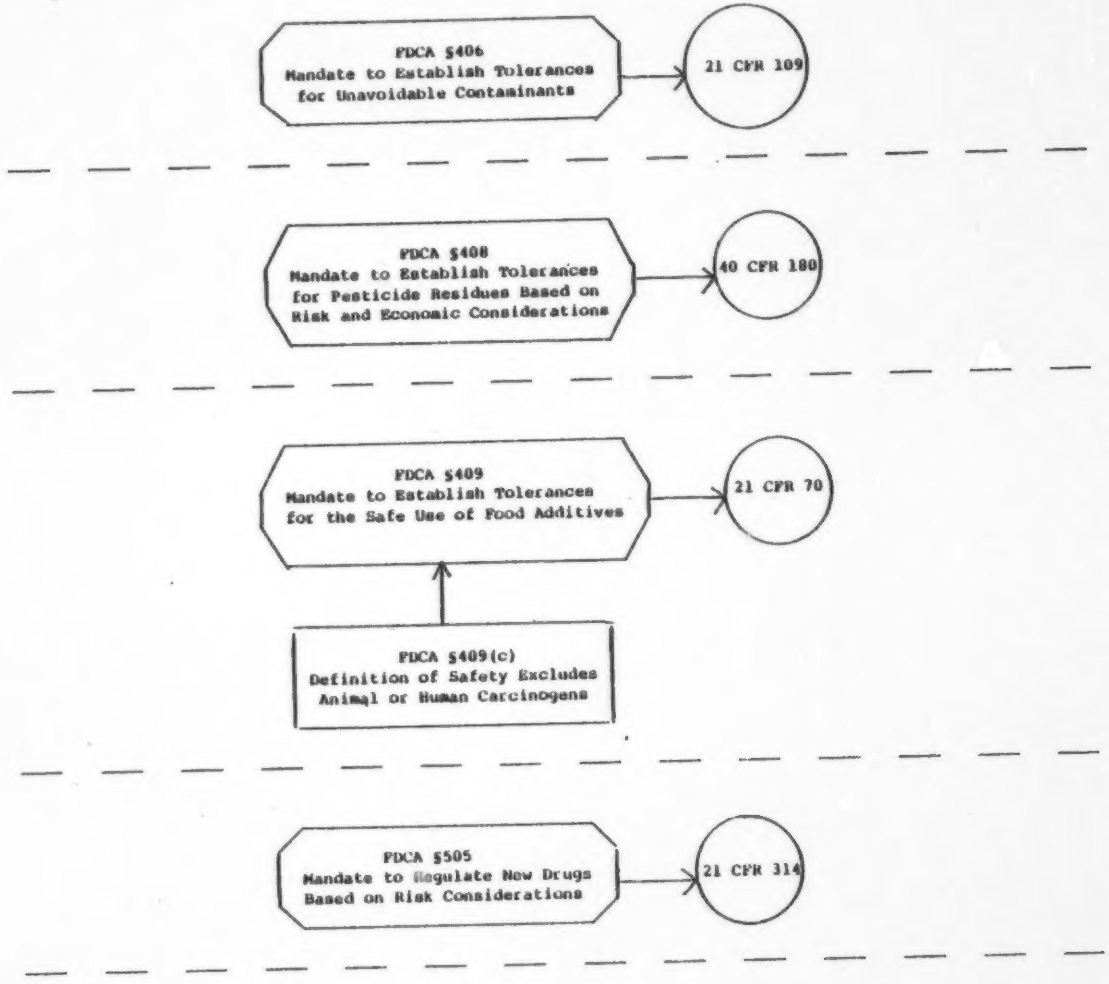
SCHEMATIC OF PORT AND WATERWAY SAFETY ACT (PWSA) DESIGNATION AUTHORITY (USCG)

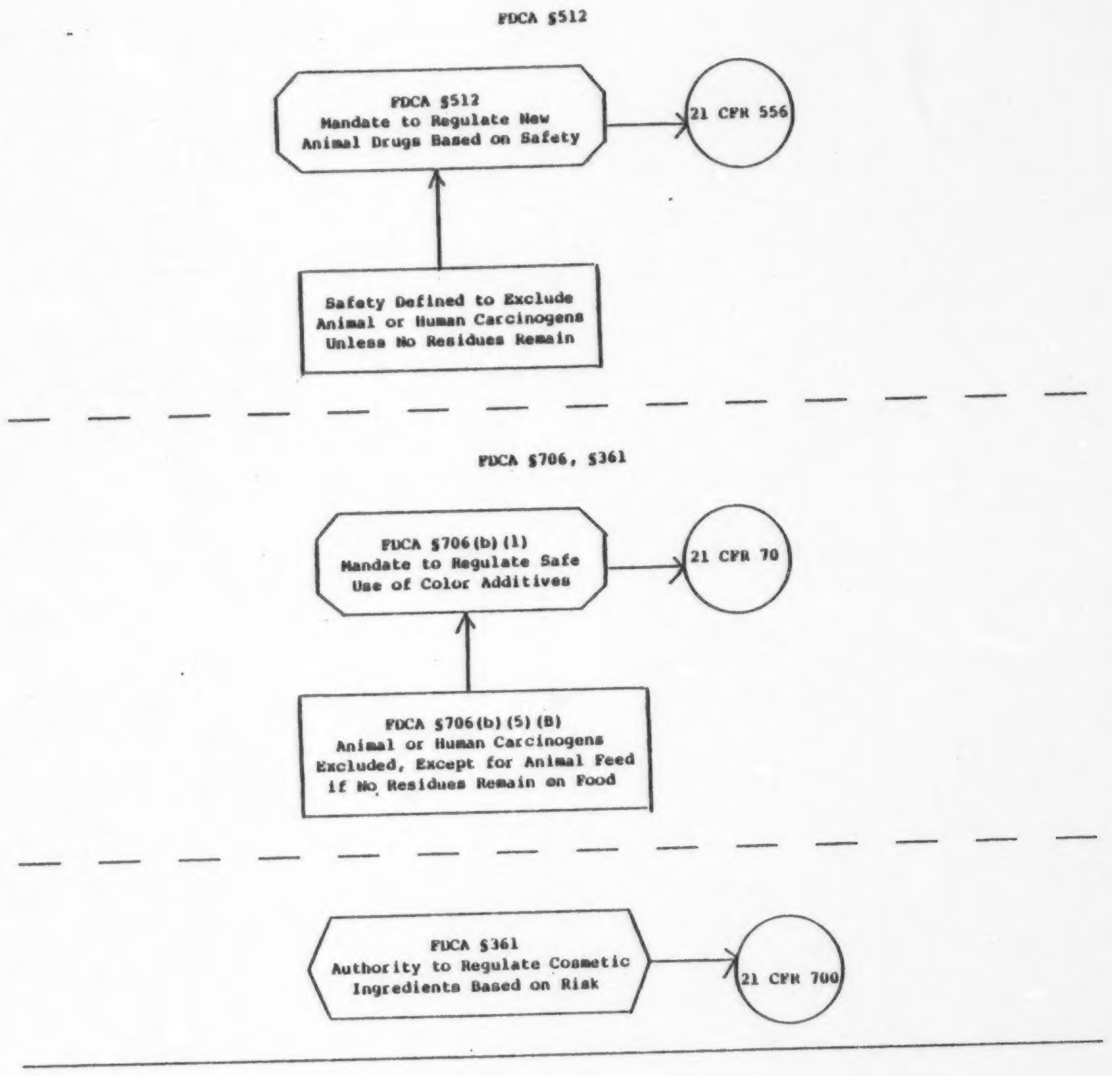
PWSA §104, §102, 33 USC §1225


PSWA §104
Regulatory Authority
Over Vessel Operations
33 CFR 126
33 USC §1225
Regulatory Authority
Over Waterfront Safety
PWSA §102(a)
Required Risk and
Economic Considerations
33 USC §1225(a)(2)(A)
References Definition of
Hazardous Material at
46 USC 391a (BFCLA)

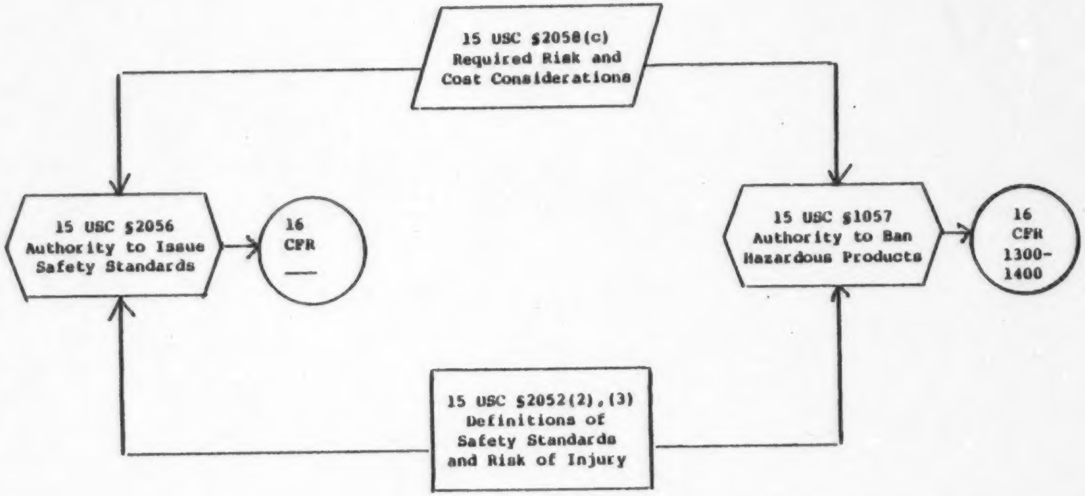
SCHEMATIC OF FOOD, DRUG, AND COSMETIC ACT (FDA) REGULATORY AUTHORITY

FDCA §406, §408, §409, §505

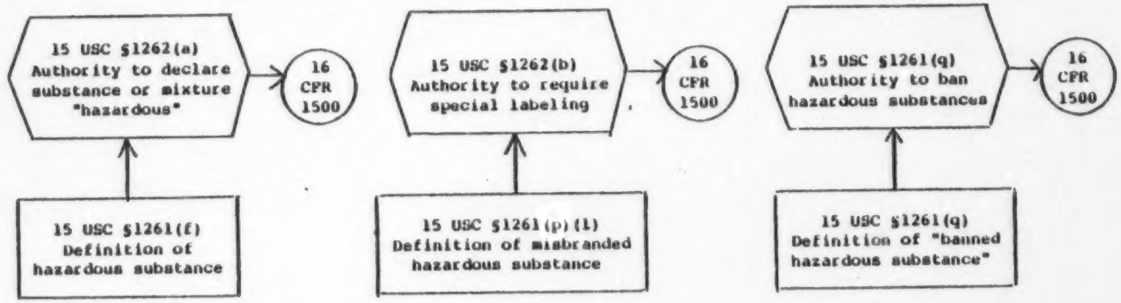

FDCA §406
Mandate to Establish Tolerances
for Unavoidable Contaminants
21 CFR 109
FDCA §408
Mandate to Establish Tolerances
for Pesticide Residues Based on
Risk and Economic Considerations
40 CFR 180
FDCA §409
Mandate to Establish Tolerances
for the Safe Use of Food Additives
21 CFR 70
FDCA §409(c)
Definition of Safety Excludes
Animal or Human Carcinogens
FDCA §505
Mandate to Regulate New Drugs
Based on Risk Considerations
21 CFR 314


FDCA §512
FDCA §512 Mandate to Regulate New Animal Drugs Based on Safety
21 CFR 556
Safety Defined to Exclude Animal or Human Carcinogens Unless No Residues Remain
FDCA §706, §361
FDCA §706(b)(1) Mandate to Regulate Safe Use of Color Additives
21 CFR 70
FDCA §706(b)(5)(B) Animal or Human Carcinogens Excluded, Except for Animal Feed if No Residues Remain on Food
FDCA §361 Authority to Regulate Cosmetic Ingredients Based on Risk
21 CFR 700

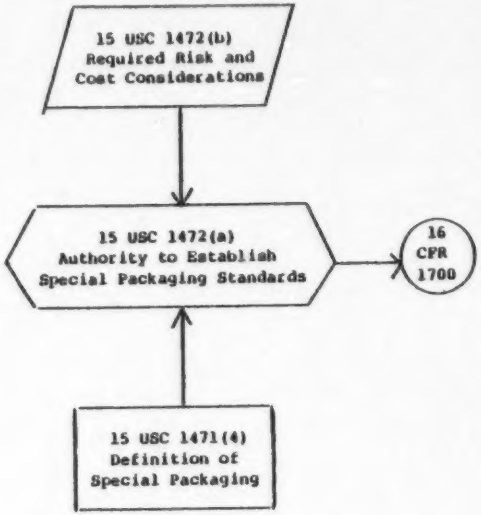
SCHEMATIC OF CONSUMER PRODUCT SAFETY ACT (CPSA) AUTHORITY


15 USC §2058(c)
Required Risk and
Cost Considerations
15 USC §2056
Authority to Issue
Safety Standards
16
CFR
___
15 USC §1057
Authority to Ban
Hazardous Products
16
CFR
1300-
1400
15 USC §2052(2),(3)
Definitions of
Safety Standards
and Risk of Injury

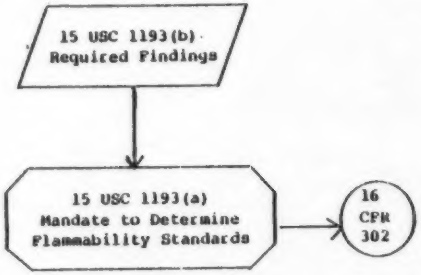
SCHEMATIC OF FEDERAL HAZARDOUS SUBSTANCES ACT (FHSA) AUTHORITY


15 USC §1262(a)
Authority to declare
substance or mixture
"hazardous"
16
CFR
1500
15 USC §1261(f)
Definition of
hazardous substance
15 USC §1262(b)
Authority to require
special labeling
16
CFR
1500
15 USC §1261(p)(1)
Definition of misbranded
hazardous substance
15 USC §1261(q)
Authority to ban
hazardous substances
16
CFR
1500
15 USC §1261(q)
Definition of "banned
hazardous substance"

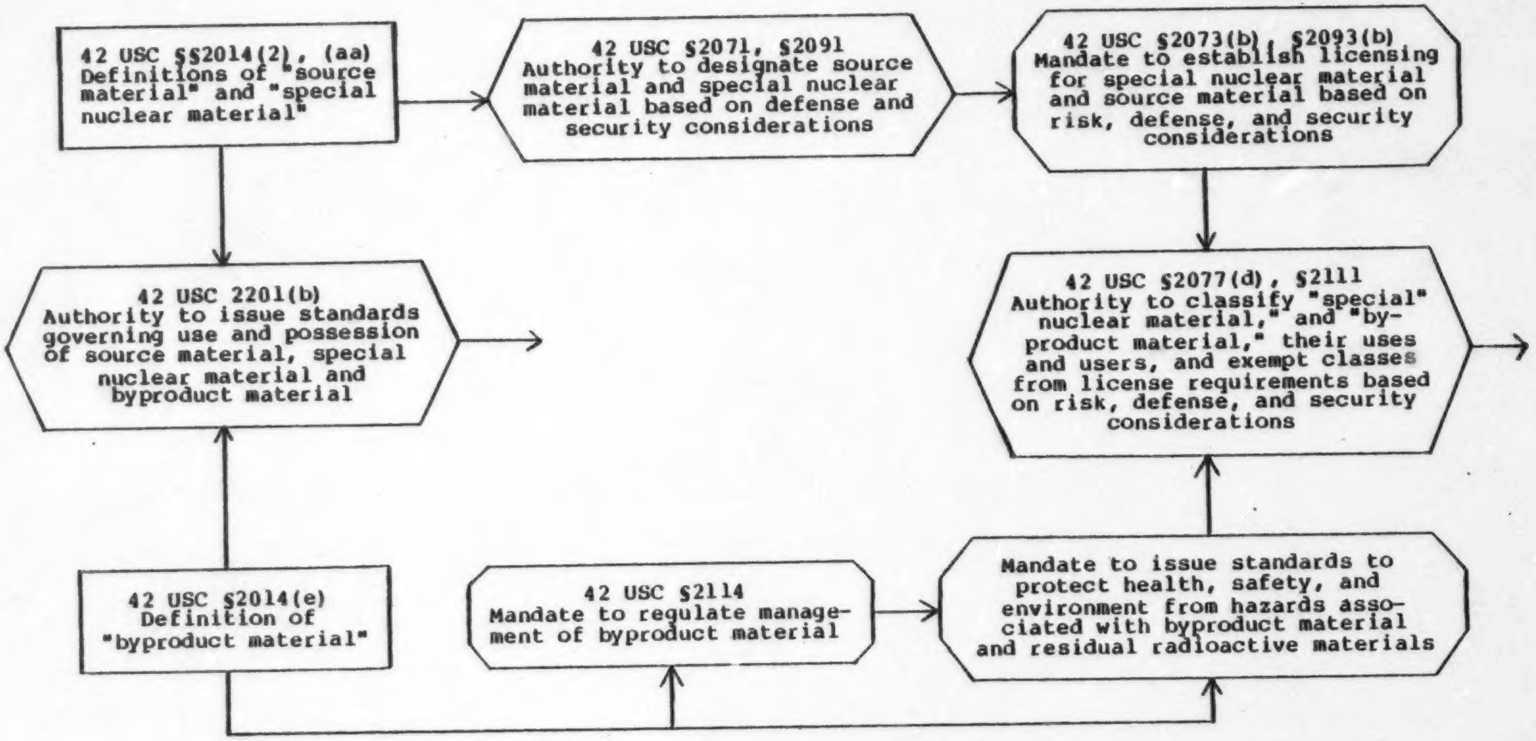
SCHEMATIC OF POISON PREVENTION PACKAGING ACT (PPPA) AUTHORITY


15 USC 1472(b)
Required Risk and
Cost Considerations
15 USC 1472(a)
Authority to Establish
Special Packaging Standards
16
CFR
1700
15 USC 1471(4)
Definition of
Special Packaging

SCHEMATIC OF FLAMMABLE FABRICS ACT (FFA) DESIGNATION/REGULATION AUTHORITY


15 USC 1193(b)
Required Findings
15 USC 1193(a)
Mandate to Determine
Flammability Standards
16
CFR
302

SCHEMATIC OF ATOMIC ENERGY ACT (AEA) DESIGNATION AUTHORITY


42 USC §§2014(2), (aa)
Definitions of "source material" and "special nuclear material"
42 USC §2071, §2091
Authority to designate source material and special nuclear material based on defense and security considerations
42 USC §2073(b), §2093(b)
Mandate to establish licensing for special nuclear material and source material based on risk, defense, and security considerations
42 USC 2201(b)
Authority to issue standards governing use and possession of source material, special nuclear material and byproduct material
42 USC §2077(d), §2111
Authority to classify "special" nuclear material," and "byproduct material," their uses and users, and exempt classes from license requirements based on risk, defense, and security considerations
42 USC §2014(e)
Definition of "byproduct material"
42 USC §2114
Mandate to regulate management of byproduct material
Mandate to issue standards to protect health, safety, and environment from hazards associated with byproduct material and residual radioactive materials